CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT
IN AND FOR PALM BEACH COUNTY, FLORIDA
CASE NO.: CL 95-1466-AH

THE STATE OF FLORIDA, et al.

Plaintiffs,

vs.

THE AMERICAN TOBACCO COMPANY, et al.,

Defendants.

DEPOSITION OF: **JOHN C. RUCKDESCHEL, M.D.**

DATE: March 23, 1997

TIME: 10:02 a.m. to 12:13 a.m.
1:16 p.m. to 5:42 p.m.

PLACE: Wilkes Reporting Service, Inc.
101 East Kennedy Boulevard
Barnett Plaza, Suite 1460
Tampa, Florida 33602

REPORTED BY: Jean M. Wilkes, RPR-CP
Notary Public
State of Florida at Large

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I N D E X

EXHIBITS

The videotaped deposition, upon oral examination, of **JOHN C. RUCKDESCHEL, M.D., F.A.C.P.**, taken on the 23rd day of March, 1997, at the offices of Wilkes Reporting Service, Inc., 101 East Kennedy Boulevard, Barnett Plaza, Suite 1460, Tampa, Florida, beginning at 10:02 a.m., before Jean M. Wilkes, RPR-CP, Notary Public in and for the State of Florida at Large.

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THE VIDEOGRAPHER: This is the videotaped deposition of Mr. John C. Ruckdeschel, M.D., taken by defendants in the matter of State of Florida, et al. versus American Tobacco Company, et al., Case Number CL-95-1466 AH.

MR. SCHLESINGER: I'll tell you. Would you be kind enough to start that all over again?

THE VIDEOGRAPHER: Sure.

MR. SCHLESINGER: It's Dr. Ruckdeschel.

THE VIDEOGRAPHER: Certainly.

(Discussion off the record.)

THE VIDEOGRAPHER: This is the videotaped deposition of Dr. John C. Ruckdeschel, M.D., taken by the defendants in the matter of State of Florida, et al. versus

American Tobacco Company, et al., Case Number CL-95-1466-AH, being held in the offices of Wilkes Reporting Service, located at 101 East Kennedy Boulevard, Suite 1460, Tampa, Florida. Today is March 23rd, 1997. The time is 10:02 a.m.

My name is Silvia Borges. I'm with the firm of Sunray Legal Videos located in Tampa, Florida, and I'm the videotape specialist.

The court reporter is Jean Wilkes with Wilkes Reporting.

Counsel will now introduce themselves.

MS. ECKELS: Lynne Eckels with the firm of Shook, Hardy & Bacon. Accompanying me is Chris Wilson, analyst for Shook, Hardy & Bacon.

MR. SCHLESINGER: My name is Sheldon J. Schlesinger for the State.

THE VIDEOGRAPHER: And the court reporter will now swear the witness.

THE COURT REPORTER: Would you raise your right hand, sir?

JOHN C. RUCKDESCHEL, M.D., F.A.C.P., being first duly sworn to testify the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION

BY MS. ECKELS:

Q. Dr. Ruckdeschel, we introduced ourselves just a few moments ago, but would you again kindly state your full name for the record, sir?

A. John C. Ruckdeschel.

Q. Dr. Ruckdeschel, I'm aware you may have given depositions previously, but I'd like to reach a few agreements with you --

A. Surely.

Q. -- that I think will allow the deposition to run smoothly.

The first is, it is important that you give me a complete verbal response. Sometimes it's easy, in a course of a deposition, for things to become conversational and for you to shake your head and say "uh-huh" or "unh-unh." But if you will give a verbal response, I would appreciate it. Will you do that, sir?

A. Certainly.

Q. It's also important, so that we get a clear record, that you and I not speak at the same time. I will endeavor to always allow you to completely finish your answer before I begin another question. If you will extend me the same courtesy,

I think that will help our court reporter. Will you do that as well?

A. I'll be happy to.

Q. Dr. Ruckdeschel, if at any time I pose a question to you that seems vague to you or you are uncertain what I am asking, please tell me and allow me an opportunity to rephrase the question. Will you do that as well?

A. I will do that.

Q. And, finally, Dr. Ruckdeschel, if at any point in time you wish to take a break, stretch your legs, confer with counsel, et cetera, just let me know and I'll be happy to accommodate you. Okay?

A. Thank you.

Q. Dr. Ruckdeschel, I'd like to start off the deposition by covering some of your background information. Can you tell me, what is your current employment?

A. Yes. I am the Director and Chief Executive Officer of the H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida here in Tampa, Florida.

Q. Do you have a business address there, Doctor?

A. Yes. It's 12902 Magnolia Drive, Tampa,

33612.

Q. How long have you been here in the Tampa area, Doctor?

A. About 5 1/2 years.

Q. During the course of that 5 1/2-year period, have you always held the same position that you just described to me with Moffitt?

A. Yes, ma'am.

Q. And is it all right with you if, during the course of the deposition, I refer to the facility as "Moffitt" --

A. Yes, ma'am.

Q. -- rather than the full --

A. Yes.

Q. -- full name? Thank you.

How old a person are you, Dr. Ruckdeschel?

A. 51.

Q. Let me briefly just reiterate, as I'm sure you've heard before, this deposition is just like testifying at the courthouse in front of a judge and the jury. To the extent that I'm going to ask you as clear questions as I can, I need you to give me as honest and as truthful response as you possibly can. Will you do that?

A. Yes, ma'am.

Q. Let's briefly cover your educational background, if we may, starting with, where did you graduate from high school?

A. Oceanside High School.

Q. And where is that located?

A. In Oceanside, New York.

Q. And what year was that, sir?

A. 1963.

Q. Did you go directly into an undergraduate program from graduation?

A. Yes, I did. I went to Rensselaer Polytechnic Institute.

Q. I'm sorry. I didn't hear. The name, again?

A. Rensselaer, R-e-n-s-s-e-l-a-e-r, Polytechnic Institute in Troy, New York. It is a science and engineering school, very similar to MIT.

Q. Thank you. And was that a full four-year undergraduate program?

A. Full four-year undergraduate. That's correct.

Q. And what degree or degrees did you attain upon completion?

A. Bachelor of Science in Biology.

Q. Okay. In approximately what year was that, sir?

A. 1967.

Q. Okay. And upon completion of that program, what did you do next?

A. Went to medical school at Albany Medical College in Albany, New York.

Q. And did you complete that educational program?

A. Yes, I did, in 1971.

Q. And what did you do immediately following completion of that program?

A. I began an internship at Johns Hopkins Hospital in Baltimore, Maryland.

Q. And how long did that internship last?

A. One year.

Q. And was there a particular field of specialty or a particular field of medicine that you concentrated in during that one-year internship?

A. Internal medicine. It was what was called then a straight medical intern.

Q. What did you do upon completion of that one year at Johns Hopkins?

A. I was offered a position in the United States Public Health Service at the National

Cancer Institute. They had a facility in Baltimore at their -- at the U.S. Public Health Service Hospital called the Baltimore Cancer Research Center, and I was offered a position there, which I accepted.

Q. And what was that position?

A. It was, at first, a staff associate, is what they called -- essentially, a fellowship period of time.

Q. And how -- what was the duration of that fellowship?

A. Three years.

Q. And, again, during the course of that three-year fellowship, was there a particular area of medicine that you concentrated in?

A. Two areas. One was -- I'm sorry -- several areas. One was, of course, medical oncology, which is what I was training in.

Secondly, was internal medicine, as a whole, because the hospital itself did not have a full range of specialists; and, therefore, we served, essentially, as our own consultants within that area of the other areas of internal medicine.

And, in addition, cancer research, particularly in the area of cancer immunology.

Q. And did you complete that three-year fellowship?

A. Yes, I did, in 1975.

Q. What did you next do professionally after completing that fellowship in '75?

A. Yes. At that time the NIH positions were offered to individuals at the end of either their first year of training, their internship, or their second year of training. Mine was offered at the end of my first year of training; and, therefore, in order to complete my certification in internal medicine and then be able to sit for my boards in medical oncology, I had to go back and do a year of residency training in general internal medicine, and I did that in 1975 to 1976 at the Harvard Hospital, Beth Israel Hospital in Boston, Massachusetts.

Q. Okay. So that was an additional year of residency. Correct?

A. That's correct.

Q. Okay. What did you do professionally following the completion of that additional year of residency at Beth Israel?

A. I moved to the Albany Medical College where I assumed the position of Assistant Professor

of Medicine in the Division of Medical Oncology.

Q. At that point, were you licensed to practice medicine in the State of New York?

A. Yes, New York and Massachusetts.

Q. Is your licensure in New York still active, Doctor?

A. Yes, it is.

Q. Is your licensure in Massachusetts still active?

A. No, it is not.

Q. What other states are you currently licensed to practice medicine in?

A. The state of Maryland, which is inactive, and the state of Florida, which is -- which is active.

Q. Have you ever applied for licensure in any other states?

A. I don't believe so, no.

Q. Okay. Are you currently -- I think this is a common term -- board certified in any particular areas of specialty?

A. Yes, in two.

Q. And what would those be, Doctor?

A. I'm board certified in internal medicine and in medical oncology.

Q. For the benefit of those that may someday hear or read this deposition, would you define for me, in basic laymen's terms, what is medical oncology?

A. Yes. Medical oncology is the application of internal medicine to the care of the cancer patient. It originally grew up in -- or around the therapeutic modality which is chemotherapy. But what has happened over the last 20 years is that the medical oncologist has become the primary care specialist, if you will, for the cancer patient, the person who helps them through both their treatment, their diagnostic phase, and their terminal phase of their illness, and manages all of the other things that happen to them while they also happen to have a malignancy.

Many people rely on their medical oncologist, basically, as their primary care physician during the period of time when their cancer is active, and so that -- that's fundamentally what the field is.

Q. And could you also define for me, Doctor, the field of internal medicine? You used that phrase as a part of that definition, but it's also a separate certification you hold.

A. Yes. Internal medicine is what I think are -- originally was described as diagnostics. It's the person who takes information from any number of thousands of sources and -- bits of information and puts that together into a diagnosis for a patient.

It also has assumed, over the last 50 years, the sum of its various subspecialties, gastroenterology, kidney disease, endocrinology, hormonal illnesses, such as thyroid, that whole array of things. And so your training is across the board in all of those nonsurgical aspects.

You learn to do -- you train in surgery as well. You learn pre and postoperative care, but you don't actually practice surgery, per se, so it is all those other areas of medicine.

Q. I believe you stated a moment ago that, upon completion of your various fellowships, internships, residency programs, that you went back to Albany Medical College and took a position there. Is that correct?

A. That's correct.

Q. What was your initial position, if you could describe it for me, when you went back to Albany Medical School?

A. Yes. I was a junior faculty member and Assistant Professor of Medicine in what was then called the Division of Oncology.

Q. Okay. And what does that mean? What type of duties did that entail?

A. That entailed, at that time, basic research. I continued to do immunology research. It entailed clinical research and cancer clinical trials. It involved the care of patients with cancer and it involved teaching medical students, residents and fellows.

Q. Could you give us, Doctor, a general understanding and definition, to differentiate between immunological research and clinical research? You just used both of those terms.

A. Yes. When I speak to immunologic research, I'm speaking to what we call "bench" research. That's actual laboratory research where one is looking at studying fundamental biologic processes, and I've been involved in that at several different levels over the years.

Clinical research is where you actually translate all of those test tube findings and animal findings into patient research, and it's -- whatever treatment we think is better or wonderful or

magnificent has to be compared, at some point in time, formally or informally, to the treatments we have available. The formal process of doing that is called clinical research, and that's been an area of expertise for 25 years.

Q. Were you involved in bench or lab research during the entire time you were at Albany Medical College?

A. Up until about the last year, yes.

Q. As a part of your lab research, were you involved in any particular animal studies?

A. As a medical student, I was involved in animal studies. As a faculty member, all of my studies were involved with human tissues but not animals.

Q. We can cover this in more detail later, but let me ask the same question in slightly broader terms. Since leaving Albany Medical College, to date, have you been involved in any laboratory research involving any particular animal studies?

A. No, I have not. Not directly.

Q. During your tenure at Albany Medical College -- and I'm talking about professionally, not as a student -- did you continue to progress and take on other responsibilities and obtain other

titles while you were there?

A. Yes, I did.

Q. What was that progression?

A. I became, in 1979, an Associate Professor of Medicine. In 1983, I believe, I went on sabbatical to the National Cancer Institute for a year.

I then returned. I was made Professor of Medicine and then was made head of the Division of Medical Oncology -- Division of Oncology.

We petitioned to have the name changed to Medical Oncology to distinguish it from surgical and radiation, and that was done.

At that time, I had developed an interest in behavioral sciences and had been doing research in that area, and so we added a section onto the division.

I was then asked to be the division head in medical oncology. At that time, the infectious disease specialists all left the institution as we were struck by the AIDS epidemic. We were just north of New York with 17 prisons in our catchment area, and we were almost overrun by it. And so the oncologists, myself in particular, had to pick up the early wave of the AIDS epidemic, and so that

came under our jurisdiction as well. So I ran the AIDS unit and the Division of Medical Oncology.

After about three or four years, we recruited someone else to head the AIDS unit and --

And then, during my -- about three or four years before I left, they began the process of -- one of several attempts to initiate a cancer center at Albany, and I was named Director of the Joint Center for Cancer and Blood Disorders in '88 or '89. I can't remember the exact year.

It was actually a fluid period of time, so I can't remember exactly which date. I'm sure I can refer to it and --

Q. I understand. I'm not trying to pinpoint you to months and dates. I'm just trying to get a general --

A. Yeah.

Q. -- feel for the history.

You mentioned, just a moment ago, Doctor, that at one point you took a one-year sabbatical to participate with the NCI.

A. That's correct.

Q. And, again, for clarification -- and I may ask you this throughout the deposition --

A. No problem.

Q. -- every time we use initials, to make sure we understand what we're talking about -- you're referring to the National Cancer Institute?

A. That's correct.

Q. What was the purpose of that one year at NCI? Was it a particular program, or was there an emphasis for that one year?

A. Yes. The -- in the period in question, I was an Associate Professor and was not particularly enthused about the administrative direction that the college was taken -- taking, and so I elected to return to basic science -- keep seeing patients, but to return more to basic science and not involved as much in the administrative duties.

And so I took the year of sabbatical. I took it with Dr. John Minna, M-i-n-n-a, and Dr. Adi Gazdar, A-d-i, G-a-z-d-a-r, both of whom -- Dr. Minna, in particular, headed the National Cancer Institute's lung cancer operations, and they were stationed at the National Naval Medical Center, commonly known as Bethesda Naval, directly across the street from the main NCI campus.

I spent a year in cell biology with them, working with -- and helping develop human lung cancer cell lines and doing some -- part of

the original group through the early and mid 1980s, defining the biology of lung cancer and the multiple genetic changes that occurred in that disease. And went back to Albany and attempted to -- and re-established a laboratory in that area; and then about two years later was raised to division head and center director there, so I eventually gave that up, just before I came down here.

Q. You mentioned previously, Doctor, that once you returned to Albany, after spending a year at NCI, that you had developed an interest in behavioral sciences.

A. Yes.

Q. Would you define or explain what behavioral sciences are?

A. Yes. In -- they're a very broad field. But in the context of what I have done, we had initially looked at issues in our -- a cancer course that we had taught and had been funded by the National Cancer Institute to develop, and we had looked at attitudes of students before and after the course and found that a very unsatisfactory measure.

We decided that attitudes were of no importance. It was actual behaviors that were of

importance. And so we began a 10-year study of physician behavior with patients. It had never been described before. These were almost field studies in the Margaret Meade tradition of being out in the field. No one had ever described what a physician does on his rounds, what they said to patients, whether they touched them, whether they sat, stood, went in the room, how long they spent. And so we defined that.

Then we looked at a whole series of studies on what impacted on those behaviors and how that impacted on physician satisfaction, and those studies continue in varying formats till today.

Q. When you returned to Albany after spending the year at NCI, and then became head of the Medical Oncology Division -- am I saying that correctly? --

A. Yes. That's correct.

Q. -- could you give me an estimate of how your time was divided between a clinical practice, i.e. seeing patients, versus administrative time, versus research laboratory time?

A. Yes. Unfortunately, only about 10 percent of my time was basic research time. Another 15 percent or so was clinical research time.

Administrative time took about another 15 percent; clinical care, about 50 percent. And then I had -- about 10 percent of my duties were in national administrative duties. I was chairman at that time of the Lung Committee, now the Thoracic Committee, the Eastern Cooperative Oncology Group, and I was also the Executive Officer of the Lung Cancer Study Group. Those are both National Cancer Institute-supported multi-institutional, what we call "cooperative groups" for performing clinical research.

Q. And during that time period, Doctor, did you also act as a consulting oncologist to other medical facilities?

A. Yes.

Q. And those would include -- and correct me if I'm leaving anything out -- a St. Mary's Hospital, Samaritan Hospital, a St. Peter's Adirondack -- I'm sorry --

A. Adirondack Medical Center.

Q. -- Adirondack -- thank you -- Medical Center, and the Community Health Plan in Lakeland?

A. Yes. That's correct.

Q. Am I leaving anything out, Doctor?

A. Yes, ma'am, the Veterans Administration

Medical Center in Albany.

Q. Thank you. And what percentage of your time would you estimate was devoted to being a consulting oncologist for those various facilities?

A. I've included that in my clinical time. The -- each of them sort of came in turn. The time at the VA would be one or two months a year, at most, where I would take a turn on rotation or teaching there or on the clinical service there. The Samaritan and St. Peter's were only for those occasional instances when our patients were admitted there.

The St. Mary's, we originally set up a Community Cancer Center there in the late 1970s or early 1980s. And then the General Hospital of Saranac Lake, which became Adirondack Medical Center, we established a cancer program there, and I would fly there approximately once a month. And each of us would, in turn, once a week go up there -- so myself, once a month -- to see patients in that facility.

Q. So the time which you devoted to those facilities as a consultant was included in the 50 percent clinical care --

A. That's correct.

Q. -- estimate that you gave me earlier?

A. That's correct.

Q. You've given me, I think, a good description, Doctor, of your various duties at Albany. How did those duties vary when you became the Director for the Joint Center of Cancer and Blood Disorders, if they changed at all?

A. Yes. The administrative time went up. The -- actually, I'm not sure the percentages changed in particular. The weeks just got longer.

Q. I understand. Did you have to eliminate any of the other categories from your schedule, that being research or clinical research?

A. Yes. That's when I began to reduce my basic research activity and to recognize that I was not going to be able to successfully pursue the basic science activities because I could not devote sufficient time to it.

Q. And so I make sure I understand you correctly, when you say "reduce your basic research," you're referring to the bench or the laboratory research?

A. Laboratory. That's correct.

Q. And was that the position you ran, as Director of the Joint Center for Cancer and Blood

Disorders, when you left Albany?

A. That's correct.

Q. Okay. And when did you leave Albany?

A. I left Albany in November or December of 1991.

Q. And why did you decide to leave Albany at that point in time, Doctor?

A. I was made a relatively spectacular job offer here in Tampa.

Q. Okay. And that's the position with Moffitt which you've already described for me?

A. That's correct.

Q. Since arriving in Tampa in -- I'm sorry -- '91?

A. I arrived here in December of '91 and formally started my position on January 1st, 1992.

Q. Okay. Since arriving at Moffitt in January of '92, has your position remained the same the entire time?

A. Yes, it has.

Q. Can you generally describe your duties and responsibilities for me at Moffitt?

A. Yes. I sustain about 10 to 15 percent time in clinical practice, limited almost exclusively to the field of lung cancer. I spend

about five percent of my time still involved in clinical and behavioral research, and the remainder of my time is administrative, running a cancer center -- a research institute and all the various facilities and et cetera that we have there.

Q. That would make approximately 80 percent dedicated -- 80 percent of your time dedicated to administrative functions. Correct? Would that --

A. Is that what that added up to?

Q. That's what it added up to on my math. Does that sound about right to you?

A. Yes.

Q. Are you teaching, Doctor?

A. Incidental to my clinical activities, yes. I see -- when I round, I will have either students or fellows or residents there as part of that. I, of course, teach in hundreds of graduate medical education programs.

Q. Help me understand, if you will, Doctor. When you say that you're spending about 10 to 15 percent of your time in a clinical practice, does that mean you're spending 10 to 15 percent of your time seeing individual patients, or is that observing groups of patients for studies? Could you give me some ideas there?

A. It's all -- it's seeing individual patients. I'm the only person in the southeast listed in Good Housekeeping and Best Doctors in America for Lung Cancer, and so I have two and three calls a day for referrals for lung cancer patients.

I cannot see them all, but we have a group that we call our Thoracic Oncology Program with four other medical oncologists, who do -- just do lung. The radiation therapists and pulmonologists who -- and we work as a group with our two -- now, three thoracic surgeons. And so one of the other members will see it, but they all -- most of them funnel through my office. So it's -- it's probably 30 hours a week, but it's -- it's still only 20 -- 15 percent, or whatever it is, of my time.

Q. And in this thoracic oncology group, there are oncologists plus what other professions?

A. There's -- 1, 2, 3, 4 -- five medical oncologists, two pulmonologists, three thoracic surgeons and one radiation oncologist, all of whom devote virtually all of their professional time to lung cancer.

Q. Would it be fair to say that this group, the thoracic oncology group that you've just

described, sees very little, if any, cancer patients, other than those presenting themselves with lung cancer?

A. Yes, we -- since we call it a thoracic group, we also see mesotheliomas, thymic, anything involving the chest, including metastatic disease to the chest where there's an -- where there's a diagnostic dilemma posed for individuals. And we see -- I see occasional other VIP patients. If the Governor's office calls and has someone, or whatever, I will generally make room on my schedule to see them. Or if Mr. Moffitt calls and says a friend has a certain kind of cancer, I will usually find a spot in my schedule, whatever that problem is.

Q. I understand. Within this thoracic oncology group, can you give me an idea of how many patients you actually see in the course of, let's say, a given month or a week, whatever is easiest for you?

A. Yes. Sure. I see anywhere from two to five new patients each week. That program sees approximately 500 new lung cancer patients. The others are fairly small numbers, but about 450 to 500 new patients each year.

I personally see about 70 or 80 new patients within that, and so my -- when I'm in town, I'll see up to four or five patients a week. There are periods when I'm out during the year at various meetings. But what we do is we have a physical area set aside, the thoracic oncology area. It operates as a practice composed of all the individuals I've told you that uses that space all during the week.

On Wednesdays we have our consultation day, our multi-disciplinary clinic day, and we will see anywhere between 13 and 15 new patients on that day. They will be seen by one of us in the group.

We break at about 1:00 for an hour and a half, discuss all the cases that were seen. And then anybody who needs to see another specialist as well, where we're going to have combined therapy, they will see that individual in the afternoon, and they may get CAT scans or biopsies or something during the course of the day, but we basically try to do all of the consultation in one day.

Q. Everyone in this thoracic oncology group is a full-time staff member of Moffitt?

A. Yes. Well, they're all faculty members at the University of South Florida. Each of them has varying amounts of other duties: some, basic

research; some operate at the VA or at the Tampa General Hospital as well, but their primary, overwhelming clinical responsibilities are through the Thoracic Oncology Program.

Q. How do most, if not all, of the patients that are seen by you and this group -- how do they reach you? How do they become introduced or get an appointment to see one of the members of this group?

A. Multiple sources. I would say a little over half of them -- probably 50 to 60 percent of them -- are referred by other physicians, either within the region, within the state, or within the -- within the country. Occasionally outside the country; Canada and South America in particular. The physicians will call, usually directly to one of us, and make arrangements in that direction.

There are a whole series of patients who will, through various means, learn of our program. As I said, we're listed heavily in Best Doctors in America, Good Housekeeping, et cetera, and they will -- they will have those lists somewhere. And increasingly, there's a group who come in off the Internet who've learned about us from there. And so they will call directly. They might call through our Cancer Answers line; and when the staff

recognizes they have lung cancer, they'll be sent to the program. Or they can call the place directly and say, "I want" -- "I have lung cancer; I want to be seen," and they'll get an appointment as well. We'll -- we'll see anyone.

Q. Okay. Is -- and I think you may have just anticipated my next question. Is there a particular criteria that this Thoracic Oncology Group at Moffitt has for determining who they will or will not see other than simply an individual presenting themselves with a diagnosis of lung cancer?

A. I think the only thing that would keep a patient -- keep us from seeing a patient is if their insurance company won't let them come there.

We'll see them anyway, but they need -- they get cautioned, then, that they do so at their own financial peril in these times. But that's the only reason we wouldn't see a patient.

Q. Do you know, Doctor, what percentage, if any, of the patients currently under the care of this Thoracic Oncology Group are Medicaid recipients?

A. I would estimate between 8 and 12 percent.

Q. And, for clarification, how do you determine -- or how do you know which ones are Medicaid patients and which ones are not?

A. We normally pay very little attention to that. It's listed on the forms. Hospital clinics have to collect certain data, and it's called a UB -- capital U, capital B -- 82 Form, and it's -- you're required to collect certain amounts of information. Who the primary insurer is is listed there. And the only time it becomes of importance is when we need a particular service, and it may or may not be available to a Medicaid patient; and, therefore, we have to work with our social work team to try to provide that service in some other way.

Q. What types of services would not -- that you may want to recommend or that anyone in your oncology group may want to recommend -- would not be available to a Medicaid recipient?

A. Occasionally, some forms of counseling or home care. I mean, they're fairly small.

Actually, the Medicaid program takes pretty good care of the patient. It doesn't pay us very well, but it does -- the patients do get good care. Most things are available to them. There's

just, like, transportation that need to be sorted out and -- excuse me. I'm sorry. Go ahead. Those are the issues.

Q. Okay. And I take it from your prior comment, there is a difference between what Medicaid will reimburse you, as a physician, to care for Medicaid patients versus what some private insurance companies will reimburse for that -- offering that same care?

A. Yes.

Q. How would you describe the difference between the two?

A. Well, it used to be an enormous difference. It is much less so in this era of managed care.

Fundamentally, Medicaid has placed restrictions on the dollar costs of outpatient care and on the number of days of hospitalization permitted. They actually reimburse us extra as a teaching hospital for the inpatient care, and we are in negotiations with the state program to break through some of the recommendations, some of the reimbursement issues on the outpatient side, as cancer is a little bit different than the traditional outpatient problems that patients face.

Q. Is there any policy, within this Thoracic Oncology Group at Moffitt, as to a quota or a limit as to how many Medicaid patients they would accept?

A. No. No, nowhere in the institution. We are -- we were founded by the state. We're a not-for-profit corporation, but we would not limit patients in any way.

Q. We discussed earlier when you were at Albany various facilities which you served as a consulting oncologist. Are there similar -- are you in a similar situation in Florida, meaning are there other facilities to which you're consulting to now?

A. Yes. I have consulting privileges at Tampa General Hospital and at the James Haley Veterans Administration Hospital across the street from the Cancer Center -- or across the street from the medical school. I don't -- I don't believe I've used either of them, given the nature of my duties, but they are available to me.

Q. You mentioned earlier that your teaching experience right now is fairly incident to your --

A. Clinical work.

Q. -- clinical work. Could I take that to mean that you're not actually doing classroom teaching at this point, or are you?

A. I would -- I usually do one or two classroom lectures a year, but very -- very minimal.

Q. I'm sure there are numerous professional associations for which you are a member. But if you could list for me, Doctor, those which you consider the ones that you are most active in.

A. The American Society of Clinical Oncology, the American Association for Cancer Research, the American College of Physicians, the American College of Chest Physicians, the Florida Society of Clinical Oncology, the Eastern Cooperative Oncology Group, the American Cancer Society.

I'm just trying to think if there are any -- oh, and the American College of Chest Physicians.

Q. Do you hold any particular offices or noteworthy positions with any of those organizations, Doctor?

A. Yes, in the -- I'm on the board of -- the local board of the American Cancer Society, the county board. I am on the Statewide Research Council, I guess it is, for the American Cancer Society. I'm the chair of the Prevention Committee for the Eastern Cooperative Oncology Group.

I also missed one. It's called the Cancer Control Research Advisory Council or CCRAB. It used to be a board, not a council, and that's -- I'm head of that. That's a gubernatorial appointment here in Florida.

I'm a fellow in the American College of Physicians and a fellow in the American College of Chest Physicians as well.

Q. You mentioned earlier, Doctor, that Moffitt is a not-for-profit facility. Correct?

A. Yes.

Q. Can you just generally describe for me how Moffitt is funded and/or supported financially?

A. Yes. The Moffitt Cancer Center receives approximately a hundred to a hundred and twenty million dollars in revenues each year, which it uses to fund the vast majority of its activities; a payroll of about 40 million dollars, and obviously much of that comes from that.

We receive now about, overall, 12 to 14 million dollars in grants, a half a million or more a year in donations, not counting long-term bequests.

We have several million in -- tied up in what are called lines, if you will, but endowed

chairs and professorships that are held in the University's foundation. And we get approximately nine to nine-and-a-half million -- it varies from eight-and-a-half through ten-and-a-half million dollars -- per year from the State of Florida as a general revenue appropriation.

Q. Okay. I think I missed something. Please help me.

Of the 100 to 120 million dollars in revenues that Moffitt sees annually, where does the bulk of that revenue come from?

A. Patients, patient care. All of it comes from patient care.

I'm sorry. We probably have a few hundred thousand dollars a year in interest, or we might sell a piece of equipment or sell a piece of property, whatever; normal course events, but they're all incidental to the patient care business.

Q. Of the 12 to 14 million that Moffitt receives annually in grants, is there any one grant or any one institution that stands out as being the primary grant donor?

A. The National Institutes of Health; in particular, the National Cancer Institute. We have over four million in grants from the National Cancer

Institute; approximately another three from other portions of the National Institutes of Health: Heart, Lung and Blood; Allergy and Infectious Diseases.

We also then have several million dollars in other either pharmaceutical grants or other government grants through the Department of Defense in particular.

Q. You mentioned to me earlier that approximately 8 to 12 percent of the patients seen by the Thoracic Oncology Group were Medicaid recipients. Do you know what the percentage of Medicaid recipients treated by Moffitt as a whole would be?

A. It's identical.

Q. It's identical, the 8 to 12 percent?

A. Yes.

Q. Do you know how that equates, Doctor, to the percentage of revenue that Moffitt receives annually as a result of Medicaid payments?

A. I don't have the -- I don't have the numbers off the top of my head. The Medicaid program pays a lower overall percentage than several of the commercial and several of the other managed-care pieces, but they're generally in

proportion to the proportion that we see them in the institution. There are what we call more "write-offs" in that area as people exhaust their benefits, but -- but increasingly that's the case with every form of insurance.

Q. What is the relationship between Moffitt and the University of South Florida regarding the funding or the financial relationship? How does that work?

A. Yes. The Cancer Center was established on land at the University. The Moffitt Cancer Center is -- in its full name -- is a private 501(c)(3) corporation that holds a 50-year lease -- renewable lease on the land and the facilities. The facilities were built by the state.

We're required to have an affiliation agreement that ties us to the University, which we, of course, do. All of us are on the faculty -- are faculty members of the University, and we sit right in the middle of the campus. But we have a separate budgeting process; and although I nominally report to the president and the dean, I don't actually report to the president or the dean. I have a Board of Directors -- or, actually, I have several. And I have a nominal reporting relationship to the

chancellor, but I don't -- but -- so that's how we sit there.

We are actually four corporations. We have a parent corporation, which is the H. Lee Moffitt Cancer Center & Research Institute, Inc., and it has three subcorporations. It's Hospital Corporation, a separate foundation, and a -- what we call our screening center where we have a full-service screening facility just off the main campus that's a separate corporation, and we can manage physician services or other services there; non-hospital-based health care services through that corporation, and I'm CEO of all of the four corporations.

Q. From the financial breakdown you gave me earlier, it seems that the State of Florida is the third largest source of annual income into Moffitt, the nine to ten million, approximately, annual, that the institute receives from the State of Texas?

A. State of Florida.

Q. I'm sorry, State of Florida.

A. Yes. That's correct.

Q. Habit. I'm from Texas. It slips right out. I'm sorry about that.

Do you know from what source of revenue

the State of Florida obtains the funds that are then passed on to Moffitt?

A. Yes. The State of Florida obtains those from the general revenues of the state. These are general revenue funds.

The original funds that built our building were obtained from the state cigarette tax, a proportion of which was diverted for two years to raise the 70 million dollars to actually construct the original facility in the early 1980s.

Q. And, to your knowledge, does the moneys obtained through cigarette taxing in Florida go into the general revenues as well now?

A. I don't know that. The state has a whole labyrinth of trust funds that the various things go into, and I -- and I'm sure its purposeful -- cannot track where all the various things go.

Q. We've discussed some of your professional associations. I'd like to discuss some of your publications.

Again, I'm sure they are voluminous, but can -- do you have an idea as to how many articles you have actually authored?

A. Yes. I usually break these out into several different areas, which I'm sure you've seen

on my CV. I'm a bit of a purist in this.

The first group are what are called peer-reviewed manuscripts, and these are manuscripts that have been submitted, if you will, competitively to various scientific journals, and which they then send out to other reviewers who are supposed to have equal expertise, and I think there are just over a hundred articles in that category.

There are another group called -- I think I have them as "Book Chapter Symposia and Invited Presentations" in my CV.

And these are talks that I will give -- be asked to give or chapters to write, et cetera, in which an editor will review them, but they don't go out in a formal competitive process, per se.

There are many times I'll be asked to participate in a symposium and the results of that symposium -- the minutes of that or the text of that will be published, and so I put them in that section. It's an old-style pure CV, if you will, in terms of what's peer-reviewed and what isn't.

Q. And in the more recent years, Doctor, has there been one primary area of interest for the peer-review articles that you have participated in?

A. There have been fundamentally two areas:

Lung cancer and behavioral studies.

Q. Earlier today when we discussed behavioral studies, it was in the context of how a doctor behaves in his interaction with a patient. When you mentioned to me that your other area of interest in your articles is behavioral sciences, which behavior -- which mode of behavior are you referring to?

A. I would say that three quarters of those articles are related to physician behavior, how that impacts patients, how we manipulate or manage physician behavior. I continue to study that area. We continue, also, to look at issues of quality of life, what that is, how to impact on that, fatigue, I -- just a whole series of issues related to how the patient experiences cancer.

Q. Do you have -- and you may or may not have an -- have a feel, Doctor, for -- of the 100 peer-review articles, how many of those have been focused on the etiology and treatment protocols for lung cancer?

A. 70, 75, somewhere in that ballpark.

Q. Within that --

A. The majority.

Q. Within that general focus of etiology and

treatment protocols for lung cancer, are there any particular articles that stand out in your mind as being the most complete and comprehensive?

A. I'd say there are about 30 articles in there that are fairly comprehensive in what they demonstrate about a particular area. There are -- there are another 30 or so that are very focused on a particular issue.

Q. Is there any one that is extremely recent that would be, let's say, the most recent one that you've put out regarding etiology and protocols for lung cancer?

A. Well, there are two. I mean, I'm now at a different point in my career, so I tend not to write the original article now. I tend to be an editor and reviewer for it now, so two areas. There's a book called Current -- I'm sorry -- a journal called Current Opinion in Oncology, which is -- which is a -- each year -- and there are four or five sections. There's one on lung and mediastinum -- the lung and mediastinum -- m-e-d-i-a-s-t-i-n-u-m -- which is basically diseases of the chest, and I'm the section editor for that. And so I see all the articles that come in in that area. We select people to review areas of that; then I review their

papers and write commentaries on that.

And in addition, my textbook, I think, is probably the largest single collection of materials. I'm coeditor of -- as you know, of the Textbook of Thoracic Oncology in both its editions.

Q. You may actually be the recipient of dozens, but of all the journals or publications that you receive on a monthly basis, which ones do you consider to be the most important?

A. I don't have -- there's, obviously, not a single journal.

Q. Sure.

A. There are an array of journals that I read and refer to at any given time, but probably the Journal of Clinical Oncology, Journal of the National Cancer Institute, Cancer Research, a journal called Lung Cancer, and Chest, as well as, you know, the New England Journal of Medicine and the Annals of Internal Medicine. Those are the ones I read on a fairly regular basis.

Q. Are there any particular authors of texts in your field which you consider to be very authoritative?

A. No. I think -- there are -- all the people who write in the area of lung cancer are

all friends. I mean, we've all known each other, trained together for years. I know their foibles; they know my foibles. They know our biases and opinions and facts and what we each know.

And I think all of us bring particular strengths to this. So I don't consider -- at the level that I operate now, I don't consider anybody authoritative or definitive more than anybody else. I mean, each of us brings a perspective and understanding of a voluminous literature to bear, and we each present that in somewhat different ways, but I -- but I don't think there's anything -- I mean, I don't turn to anything as authoritative or definitive, per se. I mean, I don't -- there's not a source when I say, "Oh, I have to know this; I have to go -- this is what I turn to," and "that's what I go to." There is no such journal, book or anything else. It's a summation of just thousands of things. That's the whole task, is keeping up with all those thousands of things.

Q. You've mentioned several medical professional associations and organizations that you're a member of. Are there any other such organizations that have a more -- a business focus that you are also involved in?

A. Yes. I'm in the American College of Physician Executives. Oh, what else am I in?

I think any other -- any number of trade groups in the hospital area, American Hospital Association, we're part of. There's several. There's -- and many of those, we're members because I'm the CEO and they -- and they come in in that fashion, and I participate in and out.

I participate heavily in the health care -- the Advisory Board, a health care consulting group that has become very popular as a source of ongoing business education in the field, primarily in that area.

Q. Are you a member of any organizations or interest groups that have, as one of their objectives, to discourage smoking in society?

A. Sure. I'm a member of the Moffitt Cancer Center. We actively try to discourage smoking.

Q. Any other organizations or entities that has that as one of their goals or objectives?

A. Yes. The -- actually, that's not a stated goal or objective of the Cancer Center, but I was a member of -- I think I still am -- as a -- I'm trying to think of the name of it in Florida. In New York it was called Tobacco or Work --

Governor's Committee on Tobacco or Health, and I also was a member of that in New York.

And there's a similar committee in Florida, and I'm -- I've been a member of that as well.

Q. Is that a committee that you're appointed to by the Governor?

A. Yes. And then the Cancer Control Research Advisory Council. It has as -- which writes the Florida Cancer Plan -- has enunciated smoking cessation as one of its major objectives.

Q. Can you tell me, Doctor, on how many previous occasions have you given deposition testimony?

A. In tobacco-related litigation or any?

Q. No, Doctor. I'm not limiting it to tobacco cases. Just how many prior depositions have you given?

A. Over about a 20-year period, I would say maybe 20 or 30 times.

Q. How many times, if at all, Doctor, have you ever testified live at trial?

A. Four or five times over that period of time.

Q. Of these four to five times you have

testified at trial, has your testimony always been in the context of being an expert witness?

A. Yes. That's correct. I'm sorry. Yes. In the testimonies, yes. There have been a couple of cases with depositions where I've been the treating physician, but that's where someone was bringing a suit against someone else and I was the treating physician for that.

Q. Correct. Of those 20 to 30 depositions, would it be correct to say that the vast majority of them have been testimony you've given as the expert witness capacity and a much smaller percentage of those where you were a treating physician?

A. Yes. 98 to 2. I mean, a very, very small percentage for treating physician.

Q. Do you keep, Doctor, anywhere within your records at your office, a list or some compilation of information on the different cases you've testified in?

A. No.

Q. Have you ever been a party to litigation?

A. No.

Q. I saw you frown. Meaning -- let me --

A. I was trying to think -- yeah. I was just trying to think what you meant by that.

Q. I understand your confusion.

A. I thought I understood it.

Q. Well, to rephrase: Have you ever been the one who sued someone else or the one being sued?

A. I think I had a $200 Small Claims Court against a car repairman in Troy, New York, at sometime in the past. That was my one experience as the claimant. I think once a patient issue was raised on side effects of treatment, but it was never -- it never came to case. It was dismissed on initial review on -- over 15 years ago.

Q. Was there ever actually a lawsuit filed?

A. No.

Q. Okay.

A. I've never had a lawsuit filed. I never instituted one or been -- or been part of one.

Q. So you've never had any type of a medical malpractice case instituted against you?

A. No.

Q. You may have just told me this, but let me ask again. I may have forgotten.

Of the four to five times that you testified at trial, each time you were serving in the capacity of an expert witness?

A. That's correct.

Q. Okay. Do you recall when that last occasion would have been where you actually testified at trial?

A. Probably six or seven years ago.

Q. Okay. Have you given any trial testimony since you relocated to Florida?

A. I don't believe so.

Q. All of your trial testimony would have been when you were in New York?

A. That's correct.

Q. Were any of those four to five trial testimonies -- or in those four to five cases in which you testified at trial, do you recall, Doctor, whether or not you offered any expert opinions regarding any smoking and health issues?

A. Actually, I believe I did not. I think these were -- none of those were lung cancer cases.

Q. Okay. Without going into the details of the four or five individually, would it be correct to say that your trial testimony has always been in a medical malpractice type of case?

A. Yes. That's correct.

Q. Okay. But none of them have been lung -- lung cancer cases?

A. Trial testimony has not, but the vast

majority of the other cases and the depositions have been in lung cancer.

Q. Okay. And I'll try to differentiate between the two and be specific with you.

A. Yes.

Q. Of the trial testimony you've given, what was the nature of them, if they weren't lung cancer cases, if you can recall?

A. Most of them were failure to diagnose or failure to pursue clinical findings, and they were in the general context of a medical oncologist. And, actually, I would pretty much review whatever was -- I was asked to do in previous years. And probably for the last 8 to 10 years have only -- I just, by dint of the amount of time I have, only accepted lung cancer cases, since that's my overwhelming area of expertise.

Q. Before today, when was the last time you gave a deposition?

A. Six to nine months ago, somewhere in that ballpark.

Q. Okay. And what case was -- what was the nature of that case and the names of the parties, if you can recall?

A. I don't remember the names of the parties

or the attorneys. It was a failure to diagnose lung cancer.

Q. And you don't recall which attorneys retained you in that matter?

A. No, I don't.

Q. You've established for me that none of your trial testimony has ever been about a lung cancer case but that several of your deposition testimonies were. Correct?

A. I may have -- I may -- may I make a correction to that?

Q. Please do.

A. I think -- for several years, I was asked by the U.S. Attorneys in -- around the country to testify in cases, and I think that one of them in the state of Washington was one that I could not return for trial to, and so I think they took -- and that was a lung cancer case and -- it was not a causation case, but it was a failure to diagnose case, nature of the disease, et cetera.

And I believe they took videotaped testimony. I believe that was played at trial, and I believe that was cited -- that was put into the record by the judge.

And then the U.S. Attorneys were -- asked

me to do several cases after that around the country, but I think -- so I think there was one trial case, but it was a video dep -- it was video testimony rather than a live testimony.

Q. And when you say "U.S. Attorney," who specifically or what branch of the government are you referring to when you say you were retained by the U.S. Attorney? Do you know?

A. Somebody who would -- I think it was the Department of Justice. It was a U.S. Attorney for Western Washington or the U.S. Attorney for the Eastern District of Oklahoma or someplace else. I didn't -- you know, I didn't pay -- or U.S. Attorney for Philadelphia or whatever, that would call and say, "Can you assist us with this case?"

Q. Do you have any documentation within your custody or control, Doctor, that would give any more specific information regarding that case in Washington?

A. I doubt it. I doubt it. Usually, my secretary is more than happy to take these voluminous files that are sent and assumes the case is settled, and they -- they join the recycling bin at that point in time.

Q. You've told me that none of your prior

trial testimony has regarded smoking and health issues. What about your prior deposition testimony? Have any of those, to your recollection, entailed smoking and health issues?

A. I'm trying to think how I want to -- want to phrase this. Many of them have included, as part of the deposition, discussions of smoking behaviors, of smoking as a causative factor in lung cancer, et cetera.

But the cases themselves have not been what you would traditionally describe as tobacco litigation cases where the issue at hand was causation. It was always the person having lung cancer; and in the process of describing that disease and how they got it, et cetera, the issues of smoking would come up during that; and I would, of course, discuss those.

Q. Of the four or five times that you have testified at trial, do you know what percentage of those cases you were testifying on behalf of the plaintiff versus testifying on behalf of the defendants?

A. I think it's almost 50-50. I really -- I mean, actually, I had one embarrassing case where I was asked by both sides and did not recognize it

until a couple of weeks into it, that I had been asked by both sides and -- it wasn't until the materials arrived. So I really don't distinguish between the two. I do whoever asks.

Q. And the same question regarding your deposition testimony?

A. Same -- absolutely the same. I make no distinction. I mean, one could be 60-40, but I -- you know, it's not because I know that or have a policy of that.

Q. Does Moffitt have a policy regarding its staff members participating in litigation?

A. No. Actually, the -- my -- the bulk of my salary comes from the State of Florida, actually through my role as a faculty member, and Moffitt reimburses the State for my time, and the State of Florida has no -- no policy. If I take time off to do something, I take that as personal leave but -- as long as I'm not using state employees, they're -- they don't -- they have no policy against it.

Parenthetically, the Cancer Center was very supportive of participating in this case, as you might imagine.

Q. That's not a surprise. Is there a policy or prohibition preventing staff members at Moffitt

from consulting for any particular industries or groups?

A. No, there's not.

Q. Is it --

A. I'm sorry. There is a -- we have a conflict of interest policy, which extends through all of senior management and -- if we are consultant, board member, and made investor over 5 percent, blah-blah-blah -- the usual litany of conflict-of-interest documents -- in any organization or company that is doing business with or trying to tempt into contract with the Cancer Center, then we must announce that at the appropriate Board meeting, both verbally and in writing, and seek the approval of the Board to continue in that, but I personally avoid all such conflicts that I know about, so I'm not in that position.

Q. Is there any particular policy or prohibition regarding staff members at Moffitt from consulting with the tobacco industry?

A. No.

Q. What agreement, if any, have you reached with plaintiff's counsel or the State of Florida regarding your reimbursement for your consulting

work and your deposition testimony and potential trial testimony in this matter?

A. I charge a flat rate of $300 per hour for all three.

Q. Do you know, to date, approximately how much time you have invested into the consulting work you've done in this matter?

A. Somewhere between 10 and 12 hours. I hurt myself there. I'm a very fast reader.

Q. You're lucky.

A. No, I'm not. Then I can read more. That's --

Q. Is there any other remuneration or promise of any other type of remuneration other than the straight financial arrangement of $300 an hour paid to you?

A. No, ma'am. No.

Q. Doctor, did you bring any documents with you today to this deposition?

A. Yes, I did.

Q. What documents did you bring with you?

A. I brought a series of materials that were provided to me by the plaintiff's counsel -- or my counsel, I guess, in this instance. I'm sorry.

Q. Do you have them with you? Can you

identify them for me, or do you have an index of them?

A. I have them behind me if I could -- I'll be happy to pull them out.

Q. I have no problem with that, but we may need to accommodate our videographer. May he --

THE VIDEOGRAPHER: Please go ahead.

Q. You may need to -- if you have to move too far away, you may have to remove your microphone.

MR. SCHLESINGER: Well, if you remember, why don't you just tell them what they are. I don't think you have to --

THE WITNESS: There's a --

MR. SCHLESINGER: -- trot them all out.

A. -- series of depositions of Dr. David Burns, B-u-r-n-s, in a 1994 case in -- of Yvonne Rogers versus R.J. Reynolds Tobacco Company, et al.

There is a -- and that includes several volumes.

Q. And that's the transcript of Dr. Burns' deposition?

A. Yes. That's correct. And then there is a deposition by Dr. Mark Green in the State of Mississippi case of Mike Moore, the Attorney General

for the State of Mississippi, versus American Tobacco Company, et al., and those are the materials that I read through.

I was also sent a series of materials, a deposition by Sir Peter Doll, both videotape and written copies of the deposition. But it became apparent to me, in going through the initial materials and in reading those, that they were repetitious, that I knew the information, and so I did not review them in preparation. I do have them here.

Q. Were you furnished by plaintiff's counsel any other documents other than these three deposition transcripts to review in preparation for your deposition?

A. No. I was -- no. I think I was just given a copy of your subpoena. I think that's the only other thing that I received.

Q. Have you ever met Dr. Burns?

A. No, I have not.

Q. Have you had any conversations with Dr. Burns at all prior to your testimony today?

A. No, I have not.

Q. Same for Dr. Green. Have you ever met or had any discussions with Dr. Green prior to your

deposition testimony today?

A. Dr. Green is a good friend. We trained together for part of our training. He was center director at the University of California at San Diego. He is currently the center director at the Medical University of South Carolina in Charleston, of their Cancer Center. We see each other frequently at meetings. We've -- I don't think we've ever coauthored a paper together, but we've certainly sat on innumerable panels and review groups together. I've not discussed this case with him, however.

Q. Where did the two of you train together?

A. We spent at least one year -- it might have been two -- at the National Cancer Institute in Baltimore. Our time there overlapped. He also is a lung cancer expert, and we -- it's a small -- it's a small fraternity or kind of -- but I guess it's not a fraternity since there are women in it, but a small group internationally. I mean, the whole international organization only has about 1500 people in it, so --

Q. I understand that you have not discussed your testimony with Dr. Green. Has Dr. Green discussed with you anything about the deposition he

gave in the Mississippi case?

A. No. No. In fact, I had not known he had done that until I received a copy of the deposition.

Q. You have outlined for me, Doctor, what attorneys have given you to review prior to your deposition. Did you review any other type of documentation or text or articles or journals on your own in preparation for this deposition?

A. No, ma'am. I carry them around in my head.

Q. You were not asked to review any particular Surgeon General Reports or anything of that nature in preparation for your testimony?

A. No, ma'am. Excuse me. I'm sorry. I believe that, in addition to Sir Peter Doll's testimony, there was a copy of the Surgeon General's Reports and another article in the materials they sent, but I did not read them or use them in preparation for this. I'm generally familiar with their content.

Q. Okay. Through documents previously produced to me, it was my understanding that you had been provided with a report called "The Report on Policy Aspects of the Smoking and Health Situation in the USA." Is that an article that you recall

reviewing?

A. No. I received it, but I didn't review it.

Q. Similarly, Doctor, did you also receive an article entitled "Cartoons, Cotton Candy and the Marlboro Man"?

A. Yes, I did.

Q. Did you review that article?

A. No.

Q. When were you first contacted, Doctor, to -- or were first approached about the possibility of serving as an expert in this matter?

A. I would have to guess about three or four months ago.

Q. Who contacted you?

A. I believe Attorney Schlesinger, and there were two other attorneys present whose names I don't remember off the top of my head. I'm sure counsel could give you their names, but I don't remember them offhand.

Q. Okay. Were you already familiar with Mr. Schlesinger, or do you know how he came to contact you?

A. No. I understand that the State of Florida, in its preparation of this suit, brought

together a team of attorneys from around the state, and it is my understanding that someone in state government or the Governor's office suggested my name, among others, as people who -- as individuals who would potentially lend support to the case scientifically or medically, and I was contacted in that context, is what I believe -- what I was told and what I actually believe.

Q. Of the attorneys that have contacted you and worked with you in preparation for your testimony, had you ever worked with any of those attorneys before?

A. No, ma'am.

Q. Were you originally contacted by phone?

A. I believe a call was made to my office to set up an appointment, but I think the initial contact was actually a meeting in my office.

Q. Okay. And -- this may be repetitious. Do you recall who attended that meeting, whether they were attorneys or not?

A. Other than Mr. Schlesinger, no. I don't remember their names.

Q. And how many such meetings, whether they were in your office or at other locations, have you had with counsel?

A. I had one meeting with counsel -- I had that first meeting in my office. I had a separate meeting a week or 10 days ago with Mr. Schlesinger, and then we met briefly before coming in here; had coffee and donuts and -- I guess that counts as a meeting.

What's the term for that, "billable hours"? Isn't that how that works? I'm sorry.

Q. At the initial meeting, what was the nature of the conversation? What were you asked to do, if anything?

A. Yes. The -- at the initial meeting, the attorneys represented themselves as part of the group that had come together to assist the State of Florida in the handling of this case. I was familiar with the case itself. I was familiar with the political issues behind it. I was, obviously, familiar with the litigation. I knew a group had been chosen.

They indicated that I had come to their attention, for obvious reasons, and would I be willing to take the time to review the materials, testify in the case, and et cetera, and I said "yes." It was actually a relatively short meeting.

Q. And then you said there was a second

meeting approximately 10 days ago?

A. Yes.

Q. Can you describe the nature and general context of that meeting?

A. Yes. Mr. Schlesinger wanted to know if I had received the materials, had read them. Did I have any questions? And we discussed, actually, in very general terms, what was likely to be the thrust of the questions, and I gave him what have -- my opinions are about those. He seemed satisfied, and that was it. You know, we just met for a very -- actually, again, less than an hour.

Q. Who was in attendance at the second meeting?

A. Just -- I believe just he and myself.

Q. Okay. Did you, by the end of that second meeting, Doctor, come to an understanding of what your scope of testimony would be in this matter, what type of opinions you would be asked to render?

A. I -- I don't -- I'm not sure. I think the limitations placed on it, between the meetings -- and I'm not sure they were that explicit -- related to the issues of speaking to the disease and overall issues related to its impact on individuals in society and with respect to my expertise in the

field as a whole, the degree, to my knowledge, of how -- the causation issues, but that I would not be testifying specifically to specific scientific data on causation, which I have not been the -- I have not produced and have not specifically reviewed for this.

Q. Okay. During the course of this deposition, I will ask you a series of questions and you will have an opportunity to explain to me all of your opinions in detail.

A. Um-hum.

Q. But at this point, if I could sort of get a bullet format of what areas of opinions you intend to render, it would be helpful. And I'll start by asking -- and please let me know if I leave anything out, Doctor.

Is it your understanding that you will be -- or do you feel prepared to render opinions regarding the diagnosis of lung cancer?

A. Yes.

Q. Is it your understanding, and are you prepared to render opinions regarding the treatment of lung cancer?

A. Yes.

Q. Are you prepared to render opinions

regarding the management of a cancer patient?

A. Yes.

Q. Are you also prepared, and do you intend to render opinions regarding the costs -- and I'm referring to the monetary costs -- affiliated with the treatment and management of a cancer patient?

A. Yes.

Q. Will you be offering opinions regarding causation of lung cancer as it relates to smoking and the cause of lung cancer?

A. I suspect that I will in the course of my testimony, yes.

Q. You mentioned to me earlier that you have reviewed the deposition transcript of Dr. Mark Green. Is that correct?

A. Yes. That's correct.

Q. Then you're aware that Dr. Green refrained from offering any causation testimony as it relates to the causation factors between -- that may exist between smoking and lung cancer. Correct?

A. I believe I remember that, yes.

Q. And are you telling me, then, that, unlike Dr. Green's testimony, you are prepared to testify regarding the causative relationship between smoking and lung cancer?

MR. SCHLESINGER: Counsel, he's already told you that.

MS. ECKELS: I just want to make sure I understand --

MR. SCHLESINGER: Dr. Green's -- Dr. Green's testimony to the contrary notwithstanding, which is neither relevant nor material to any of the opinions which he has, and therefore I object to your question, as he has already told you that he is going to testify as far as causation is concerned.

BY MS. ECKELS:

Q. And, Dr. Ruckdeschel, I'm going to endeavor, to the best of my ability, not to repeat myself during the course of the day. But, from time to time -- I just want to make sure I understand what you're telling me.

A. Yes.

Q. Are you prepared to render opinions, Doctor, on the causative relationship between cigarette smoking and lung cancer?

A. Yes, I am, and I'm prepared to speak to those issues that I see them, as a clinician, as someone who has been involved in basic scientist -- as someone who has been intimately involved in

this for 20 or 25 years. I think it's a fairly straightforward relationship. I will speak to that.

I cannot speak to the individual animal or data or the individual epidemiologic studies, but the summation of all of those that I have reviewed and been part of for the last 20, 25 years have led me to opinions about causation that I think are fairly straightforward.

Q. You've told me that you're prepared to render opinions about diagnosis, treatment, management, costs, and causation. Are you prepared, and do you intend to offer expert opinions on any other aspects of a smoking and health issue?

A. Do you have any in mind? I'm not sure I --

Q. Absolutely. Let me go through a list --

A. Sure.

Q. -- and not to -- perhaps this will help narrow things down.

Do you intend, Doctor, to offer any expert opinions, or do you consider yourself an expert in surgery?

MR. SCHLESINGER: Which is it that you want to know, Counsel? Do you want to know whether or not he considers himself an expert

or do you want to know whether or not he intends to offer opinions in that regard? Your question is compound. I think you ought to decide which of the two questions you want answered.

MS. ECKELS: I'll answer it -- I'll ask them both separately.

BY MS. ECKELS:

Q. I guess I was assuming that if you didn't consider yourself an expert, you wouldn't offer an expert opinion, but let me ask them separately.

Do you consider yourself an expert in the area of surgery?

A. Yes, in a very unique way as a non-surgeon, in that management of lung cancer is heavily involved with surgery, thoracic surgery in particular. I was the -- wrote the paper that led to the founding of the lung cancer study group, which was a group of thoracic surgeons formed by the National Cancer Institute.

When those cooperative studies from our early work in Albany were finished, I became the executive officer of the group, and so I've had a unique -- almost unique role as a medical oncologist in having to review, lead, the long scientific

discussions -- tedious scientific discussions about the nuances of surgery in the management of lung cancer.

Q. Being that you consider yourself an expert in the field of surgery, do you intend to offer opinions -- expert opinions in this matter regarding thoracic surgery as it relates to the treatment of lung cancer?

A. Yes, I do. But, again, not to the specifics of the -- of how I would perform the procedure, since I don't perform the procedure. But when is the procedure indicated, what types of surgery, under what ground rules and what are the expectations that one should have from that and what are the nuances of that therapeutic modality as it applies to the management of lung cancer patients.

Q. Do you consider yourself an expert in the area of pathology?

A. If I could give exactly the same reply and substitute the word "pathology" for thoracic surgery -- again, in my role, both in the Lung Cancer Study Group and in the Eastern Cooperative Oncology Group, I've had to review pathology. I review it every week, every day, literally in my practice. How it fits -- I have published in the

area of pathology and nuances of pathology in lung cancer. And, in fact, Dr. Gazdar, who I did a good portion of my sabbatical with, is a pathologist, and those issues -- and, in fact, have published again in the issues of immunohistochemical -- i-m-m-u-n-o-h-i-s-t-o, chemical -- variations in lung cancer and its effect on prognosis.

So, again, although I am not a board certified pathologist, don't do pathology every day, I have an extensive understanding of its -- of its role and its impact and would consider myself an expert in that area.

Q. And, similarly, do you intend to offer expert opinions regarding pathology in this matter?

A. Yes.

Q. Do you consider yourself an expert in the field of epidemiology?

A. I would give the same answer. Do you want me to track through that? It's -- it's the same thing. I use it as part of my work in this, and have considerable familiarity with it and have worked closely in the epidemiologic aspects of this disease.

Q. Are you prepared to give expert testimony regarding epidemiology in this matter?

A. Again -- yes, but only so far as it impacts on the disease itself, not specific to the techniques of epidemiologic research.

Q. Do you consider yourself an expert in the field of statistics?

A. Same answer.

Q. Do you consider yourself to be an expert in the field of psychiatry?

A. The broad field of psychiatry, no. As far as the psychological and psychiatric impact of cancer on the patient, on the staff, on the family, the impact of the disease, both psychiatrically and psychologically, yes, I think I am an expert in that area, and I will be prepared to offer testimony in that regard.

Q. Do you consider yourself an expert in the field of pharmacology?

A. Really, same answer. I mean, I've worked in the area of drug development, drug design, drug testing, all of which are parts of pharmacology. I will not speak to specific issues of pharmacologic tests, nor am I a pharmacologist, specifically, by training, but have long experience in how to apply those results to the field of lung cancer and have published in that area as well.

Q. Do you consider yourself to be an expert in the field of psychopharmacology?

A. Tell me what you mean by "psychopharmacology." That's a --

Q. Well, in my layman's --

A. Yes, that's --

Q. -- terms, a psychopharmacologist is a person who is an expert in the field of drugs which are prescribed to an individual for the treatment of a mental disorder or an expert in the field of the use of drugs that may have a mind-altering effect. Using that, perhaps, rough working definition, would you consider yourself an expert in that field?

A. No.

Q. Do you consider yourself an expert in the field of addiction or in the treatment of substance abuse?

A. No. I've had experience with it as a -- in my internal medicine side of what I do, but not as an expert in that area.

Q. Since you do not consider yourself an expert in that area, is it accurate to say that you do not intend to offer expert opinions regarding addiction issues?

A. To the extent that smoking behaviors are

addictive and that that addiction is part of the problem in smoking cessation, I will discuss those and offer expert opinion in those areas. With respect to a broad expertise in addiction behaviors, I will not.

And I think I should amend my answer on psychopharmacology, really, to the same; that, as they impact on smoking behaviors in patients who go on to get pulmonary diseases, cardiovascular diseases, vascular diseases and lung cancer, I am familiar with those, issues related to those. I am just not -- I have not had as broad a training in those areas and have not published in those areas where I have in several of the other areas. But to the effect -- to the extent that they impact on the individual risks that a patient accumulates and how they accumulate those risks, I will -- I feel I can offer expert opinion in that and will do so -- or and I'm prepared to do so.

Q. And that's in the field of psychopharmacology?

A. Yes, as well as the addiction behaviors.

Q. Okay. Have you ever published on the subject of addiction?

A. No.

Q. Have you ever given any presentations, speeches, or taught any courses on the subject of addiction?

A. I've given -- parts of numerous talks have been on smoking behaviors and difficulties with cessation. That's part of the introduction to several talks on occupational causes of lung cancer and also to the topic itself. I mean, it's a frequent introductory topic for me and -- as I lead into the disease.

Q. You've mentioned to me earlier in the deposition, Doctor, that you have always had an interest in behavioral sciences and have been a participant in various studies that relate to behavioral sciences. Correct?

A. That's correct.

Q. Have you been a participant in any behavioral studies that relate to addiction?

A. Smoking addiction, yes.

Q. When was the last time you participated in a study that was -- whose -- which focused on smoking addiction?

A. Actually, I'm currently participating in that. We are -- we have brought a new faculty member on board whose whole work is in the area of

smoking cessation, and I will be collaborating with him peripherally in -- in those works.

Q. And who is this individual?

A. Dr. Thomas Brandon, B-r-a-n-d-o-n.

Q. And what type of physician is Dr. Brandon?

A. He's a psychologist. He's not a physician, so he's a Ph.D.

Q. Thank you. Has -- is there a name for this study that -- so I can refer to it by name?

A. No. No.

Q. Has the study that you've just mentioned with Dr. Brandon -- has that begun?

A. No. He arrives --

Q. When is it --

A. He arrives July 1st. In the process of his -- I'm very -- maybe it's -- be -- have specificity here.

It is my firm belief, as Director, that our efforts in smoking cessation need to be at the forefront. And rather than have that be solely a treatment option which we offer to patients, which we have done for many years, we have elected to invest in smoking cessation research, per se, and I've -- and so that's -- those are the

collaborations with Dr. Brandon. I'll probably -- I will be peripherally involved in the actual research for that, but have been -- many of the issues related to addictive behaviors around tobacco are some that I've been intimately involved in, in those behavioral studies over the years.

Q. Do you consider yourself an expert in the area of consumer behavior?

A. Only to the extent I'm -- that I'm a consumer. No, I'm sorry. I take that back. Within the area of -- of the medical consumer, I have now had to become an expert on that, as we attempt to market and differentiate an academic health center product in the marketplace. And so I've had numerous talks, lectures, readings in the area of marketing, especially as to how it relates to medical marketing and how consumers react to certain messages and the techniques of focus groups and how they can be employed and used.

So, to that extent, yes, I'm prepared to offer expert opinion as to what I have seen and learned and experienced and my own opinions in that area.

Q. I believe I understand what you're telling me, and that is that you consider yourself

an expert in the field of consumer behavior and marketing of -- I'll use your own term, "medical product." Correct? I think I borrowed your term.

A. Yeah. If I did, and if that was misleading, let me make sure I expand upon that.

It's not medical products, per se. It is the broad range of how people respond to medical messages. It, in fact -- there is a -- that field within the area of public health is called "social marketing." I now sit on the editorial board of Social Marketing Quarterly, and that's an integral part of research that we're doing in our -- some further physician behavior/patient interaction studies that we're doing.

And so I have, actually, a fairly good understanding and a fairly good expertise in the area of social marketing and how people are influenced, whether you call it marketing or advertising, or whatever else. But the scientific term, if you will, "social marketing," is the one I would apply to that. And, yes, I think I have expertise in that area and I'm prepared to offer opinions to that effect.

Q. Do you consider yourself to be an expert in the area of consumer behavior and marketing as it

applies to tobacco products?

A. I consider that part of the broader answer that I just gave; and so within that context, yes. It's certainly an example that we use many times.

Q. Do you consider yourself an expert in the area of cigarette design or manufacturing?

A. Only to the extent of how it impacts on the patient. We've had extensive discussions over the years about the differences in histology we're seeing in lung cancer and the potential role of filters in performing that -- in causing that. I have no specific knowledge about how cigarettes are manufactured or specifically designed, other than having seen it on television. But other than that, I have no specific expertise.

But how the changes that have been -- however they've been done, however they -- how they impact on people, yes, as part of their difficulties in stopping smoking and part -- also, how they affect the type of lung cancer they get. Yes, I am prepared to -- I have expert opinions on those and will -- and I'm prepared to testify to that.

Q. Do you consider yourself an expert in the field of medical economics?

A. Really, the same answer. As a CEO, yes, I've -- I better be, or I'm in trouble, so yes.

Q. Do you --

A. And I'm prepared to testify to the areas of medical economics as they pertain, primarily, to the provision of cancer care.

Q. Do you consider yourself to be an expert on the operation and economics of the Florida Medicaid system?

A. I think I have a broad understanding of it and some very specific understandings and interactions with it. There are, obviously, details of the law that I am not familiar with on a day-to-day basis; but as CEO of an institution in Florida, have to have a significant understanding of it. I chaired a meeting of the Cancer Center directors around the state, with the state Medicaid agency, attempting to establish an alternative services network in the Medicaid system with them and at their request. So I have quite a broad -- as good an understanding as anyone of the Florida Medicaid system.

Q. And are you -- similarly, are you prepared to render expert opinions in this case regarding the economics of the Florida Medicaid

system?

A. Yes, as they pertain to the care of the patient with cancer. I, obviously, have no knowledge of how those impact on other areas.

Q. And I believe you indicated to me earlier in our initial general discussion that you do consider yourself to be an expert and do intend to render opinions regarding the costs affiliated with the treatment of a cancer patient?

A. Absolutely.

Q. Okay. Well, I think I've done my best to try to give you sort of a laundry list of areas in which you are an expert. Doctor, have I failed to mention any particular area in which you consider yourself an expert and for which you are prepared and intend to render expert opinions in this matter?

A. No. I think that the other areas that are traditionally included here are the areas of radiation oncology and radiology, per se, and the answer would be the same as for thoracic surgery and pathology. I'm intimately involved in their use, although I'm not board certified in either.

Q. Would you include any other areas, Doctor, in which you consider yourself to be an expert and prepared to render expert opinions?

A. I don't believe so. Not that I remember at this time.

MS. ECKELS: I'd like a quick rest room break. Is that okay?

MR. SCHLESINGER: Great with me.

MS. ECKELS: Very good. Let's go off the record for a few minutes.

THE VIDEOGRAPHER: It's 11:40. We're off the record.

(There was a recess from 11:40 a.m. until 11:53 p.m.)

THE VIDEOGRAPHER: It's 11:53. We're back on the record.

BY MS. ECKELS:

Q. Dr. Ruckdeschel, do you now or have you ever smoked?

A. No, other than the, you know, half a dozen 12-year-old cigarettes, but no.

Q. Do any of your family members or friends now -- or have they ever smoked in the past?

MR. SCHLESINGER: Well, Counsel, I have an objection to that question, and that being that his family and his friends have a right of privacy. That question is invasive of their right of privacy. If he prefers to answer that

question, that's fine. But if he doesn't, I think that privilege can be asserted to allow him not to ask -- answer.

THE WITNESS: My son continues to smoke. My son was initially attracted to Camels; thought the Joe Camel ads were cute. He is now fully addicted to cigarette smoking; has had a very difficult time stopping on the times he's made an attempt.

My wife was a heavy smoker for many years. She stopped about a year or two after we were married, which was 10 years ago, and she did so through the American Cancer Society programs. Had a difficult time in -- in so doing, but has remained tobacco free now for about five or six years, seven years, whatever that is.

BY MS. ECKELS:

Q. Do you know at what age your son started smoking?

A. I think about 16.

Q. How old is he now?

A. 21.

Q. Have you participated in any attempts to assist him in quitting before?

A. Yes, I have.

Q. And could you describe those for me?

A. Well, initially they were just short of bodily harm suggestions. Those were ineffective, as they always are. And, therefore, other than discussions of it, was not particularly able to influence that in the early period of it.

The -- although we had numerous discussions about the ill effects of the -- of smoking itself, both short-term and long-term, and also how stupid it was, for he is a very cynical consumer of other advertising to be so gulled by the advertising for tobacco products, which he actually relatively easily admitted that he was.

Two summers ago, when he was at -- here in Tampa -- or it might have been three summers ago -- we made an attempt at using the nicotine patch, and he was able to stop smoking using that.

However, when he returned to school and all of his friends were smoking around him, he resumed his smoking habit, and he's not been at home for a prolonged period of time since then to make another attempt at it.

Q. Would it be correct to say, Doctor, that you have done everything you can to make your son

aware of the risk factors affiliated with cigarette smoking?

A. Yes. That's true.

Actually, if I could complete that answer. The -- he is, himself, poignantly aware, from school and from his own reading, of the dangers, the risks and all the problems. He finds that he is just -- he is not physically able to stop.

Q. You mentioned to me that your wife stopped smoking through, I think you said, an American Cancer Society program. Did that entail the use of the nicotine patch?

A. No, it did not.

Q. What did that program encompass?

A. I can't remember what they called it, Smoke-Free or Smoke-Enders, or whatever it was. But, fundamentally, if -- let me -- I have to back up a second in order to answer that, but there is a body of knowledge on smoking cessation that was first proposed by a Dr. Prochaska, P-r-o-c-h-a-s-k-a, from Rhode Island that said the message -- the way you help someone stop smoking depends on -- and this applies to other health behaviors as well but in smoking in particular -- is

geared -- the message you give them is geared to the stage -- the readiness stage that they are in for stopping.

So if you have someone who says, "I love smoking; I love the taste. I don't have any intention or desire to stop," that the message to get them to stop is very different from the one you give someone who says, "I desperately want to stop smoking. I have not been able to."

And there's a -- obviously, a spectrum of change in between -- it's called Change Readiness Theory -- on --

My wife was in the former category where she loved to smoke cigarettes until we got married. And then, after being with me at hundreds of Lung Cancer meetings around the world and talks, realized that this was pretty stupid of her, to be smoking, and was desperately trying to stop, but had a very difficult time with it.

And so the American Cancer Society program is -- that program was focused on people who were in that particular situation, and it turned out that the process of explaining what the side effects and what the urges -- the side effects of stopping would be and what the urges were and how to overcome

them -- and I think they tried to use Nicorette gum, which was available at the time. This was before the patches were available. She found that distasteful and a little bit unseemly and, therefore, struggled through it, and those of us around her struggled through it for several weeks until she was able to stop. But none of us would have described it as a pleasant process.

Q. As your son was growing up, during his childhood years, was there anyone in the house -- in his household who was a smoker?

MR. SCHLESINGER: You see, that's the problem with -- with invading one's privacy, and that's why I raised that objection, but it's entirely up to you, Doctor.

A. Yes. I was divorced when he was -- hmm, seven or eight, somewhere in that -- it could have been a little bit -- eight or nine -- and then remarried when he was twelve or thirteen, somewhere in that ballpark. And so for the first -- for the period of time that I was dating my wife and the first year or two we were married, he saw her smoke, and was merciless, along with his sister, in denouncing her for doing so. They used to break her cigarettes. They used to pour things in her

cigarette packs. I mean, they would do everything they could to get her to stop smoking.

Q. Did his natural mother smoke?

A. No.

Q. Has your daughter ever smoked?

A. No, not to my knowledge. And she does spend prolonged periods with us here in Tampa, and -- and I've never seen her smoke or be so inclined.

Q. Doctor, you have -- together, I think, we have come up with an outline, if you will, or a list of the various areas in which you consider yourself to be an expert, and you have told me which of those areas you intend to offer expert opinion testimony. Correct?

A. That's correct.

Q. Have we come up with a fairly -- a comprehensive list, to the best of your knowledge, of the various areas in which you intend to testify about?

A. I believe we have, yes.

Q. Okay. I would like, at this point, Doctor, to start going back over that list and to determine from you exactly what your opinions are in those various areas. And I preface this just so you'll sort of know where I'm going with the

questions today.

A. Sure. No problem.

Q. I think -- I frequently find that helpful.

The first area of testimony that you mentioned to me was that you felt that you were an expert in, and would be prepared to give expert testimony regarding, the diagnosis of a cancer patient.

A. Yes.

Q. And I think, given your history, and for purposes of this conversation, let me tell you, I'm always going to be referring to lung cancer.

A. Okay.

Q. If I deviate from lung cancer, I will be specific with you and tell you.

A. Okay.

Q. Can we have that understanding?

A. That's fine.

MR. SCHLESINGER: Let me tell you this, Counsel. If you're going to confine your interrogation, as far as lung cancer is concerned, it's not our intention to confine his expertise to that particular area of pathology, just so long as you're advised.

MS. ECKELS: I appreciate that.

BY MS. ECKELS:

Q. And, as we go through them, I will ask you, Doctor, if your opinions differ or vary any as it would pertain to other types of cancer other than lung cancer. But as we begin each discussion --

A. Okay.

Q. -- I will be focusing on lung cancer. Is that okay with you?

A. That's fine with me, and I will -- whenever I go off of lung cancer to make a point, I will try to make that clear.

Q. That would be very helpful. As I said --

A. Excuse me.

Q. As I believe I said, the first area that we talked about or that you mentioned that you felt you were an expert in and that you would be willing to offer expert opinion testimony was in the area of diagnosis. Can you describe for me, generally, Doctor, what are the methods by which lung cancer is diagnosed in a patient?

A. A proportion of patients -- approximately 30 percent -- will have a chest x-ray taken for other reasons -- cataract surgery, heart surgery, routine examination, or whatever -- and a nodule or

an abnormal shadow on that chest x-ray will be appreciated.

The remaining 70 or so percent of people will present with a symptom. Most of those will present with one or another pulmonary symptom, cough, shortness of breath, sputum production, eventually hoarseness or bleeding, hemoptysis -- h-e-m-o-p-t-y-s-i-s, as it's called.

And then, further on, as the disease spreads, various lumps and various enlarged lymph nodes, back pain, headaches, double vision, confusion, weight loss and just constitutional symptoms of weakness, loss of appetite.

Since the disease can go pretty much anywhere, it can present in pretty much any fashion. So that's the general presenting characteristics of it.

Q. And what tools, other than chest x-ray, are the tools that you rely upon in making a diagnosis of lung cancer?

A. We use -- and I will, for clarity -- as part of the group, the thoracic group that I work with, I will use the term "we" instead of myself alone, and try to distinguish, so I'm not going back and forth about which test I actually do versus

which one I use in that, if that's all right with you.

Q. I will understand that the "we" means the Thoracic Oncology Group that you practice with at Moffitt.

A. Participate in, okay. We use primarily the chest CAT scan, to the degree that it includes the abdominal organs, the liver and adrenal, as well. We use mediastinoscopy -- m-e-d-i-a-s-t-i-n-o-s-c-o-p-y -- and mediastinotomy -- o-t-o-m-y on the end of that.

We use exploratory thoracotomy, bronchoscopy. We use MRI on occasion as needed in the chest. We use it for the spine and the brain, and we use routine blood tests. And then, depending -- it's a very complex algorithm, which actually we presented at -- we were asked to present in the educational session at the American Society of Clinical Oncology last year -- about when you branch off to do more sophisticated pulmonary function testing, more sophisticated cardiac testing, in order to assess whether someone can tolerate destruction of some portion of their lung either by surgery or radiation therapy. So those are the -- the major tests that we use. I can go down any of

those pathways you want, but it's a pretty complex diversion.

Q. Do you use bronchial washings at all as a --

A. Yes. It's part of bronchoscopy, bronchial washings, bronchial lavage -- oh, I'm sorry -- transbronchial biopsies, any -- I include that under the term of bronchoscopy. We use fine needle aspirations. There's not a technique we don't use in terms of doing that other than PET scanning, which we don't think adds anything in particular.

Q. Would you agree with me, Doctor, that lung cancer is a multifactorial process?

A. I think, in the broad sense, yes. And by that, I mean that it's not that it is caused by -- individually, by a whole series of different things, so that each of them might be said to cause that individually, but by a summation of multiple factors that lead to an accumulation of genetic changes within the cell that obviously -- that flip it from irritated but nonmalignant to malignant and permanently so.

So if that's the context of multifactorial, that's -- I would agree with you.

Q. What type of classifications of cancer are there -- or can be reached as a result of using these various diagnostic tools?

A. We do two things, which I would explain to a layman or to a patient, as we need to understand what it is and where it is. And so, using those tools, we determine exactly which histology -- what it looks like under the microscope, which variation of lung cancer it is.

Now, I would say up until the last several years, that has entailed a great deal of our time and with a great deal of splitting of differences between the various cell types of lung cancer, between small cell and the ones that are described as non-small cells.

But, I think as therapy has improved over the last five to six years, there's really increasingly little difference between them in outcome. But we like to know, because we treat them a little bit differently, what they are under the microscope.

Secondly, it's where it is, and that's a process called "staging." And, again, all of those procedures are used to determine where the cancer may have spread. We use it to determine, for

example, the likelihood that it has spread elsewhere in the body. So that if we find a very small cancer and no evidence of spread to lymph nodes, we presume that the likelihood of spread elsewhere is low, in the 20 to 25 percent range.

The second the first lymph node shows up, it's 60 percent chance of having spread. And the second the next set of lymph nodes are involved, it's 90 percent, so we -- that's the process called "staging." And, again, I can go off into any level of detail on that and have published extensively in that area.

Q. The first thing that you told me that is determined as a result -- is the results you get from the various diagnostic tools is the histology.

A. That's correct.

Q. And that tells you the various cell types. Correct?

A. That's correct.

Q. And you mentioned small cell and non-small cell. Correct?

A. That's correct.

Q. What types of cells are included in the non-small cell category?

A. Everything but small cell. That

includes --

Q. Okay. And, generally, in lung cancer, what would that include?

A. That includes, commonly, squamous cancers, adenocarcinomas, large cell carcinomas, bronchioalveolar -- b-r-o-n-c-h-o-a-l-v-e-o-l-a-r-- carcinomas, and then a whole series of very uncommon little ones, like clear cell carcinomas and spindle -- there -- there are just very rare variations on that.

And then a sizable component of mixed ones, where there are mixtures of the various types that are present.

Q. Are there some of these cell types, Doctor, which are more statistically associated with cigarette smoking than others?

A. It's important to make a -- to be sure which end of this you're coming with. Every one of those cell types is associated with cigarette smoking.

On the other hand, if you have someone who is a total nonsmoker, not exposed to environmental smoke at all, who happens to be one of the rare birds that develops a lung cancer without smoking exposure, and they are present, then they

tend to have adenocarcinomas and they tend to have bronchioalveolar carcinomas in particular, so that's it.

So all of them are associated with it. But if you come in the other direction of a true nonsmoker, nonexposed person, they will tend to have adenocarcinomas.

Q. Okay. I've got some followup questions for you, but I believe we're about to run out of time on the video tape.

MS. ECKELS: Is that correct?

THE VIDEOGRAPHER: Yes.

MS. ECKELS: Do we need to stop?

THE VIDEOGRAPHER: Yes. The time is 12:13. This is the end of the first tape of the deposition of Dr. Ruckdeschel.

MR. SCHLESINGER: This may be a good time to break. So why don't we take a break now and come back in a half hour. That'll be about -- let's see -- that's not right, that --

MS. ECKELS: I've got approximately 12:15 on my watch.

MR. SCHLESINGER: 12:15.

THE WITNESS: 12:15. Quarter to one is fine with us.

MR. SCHLESINGER: Well, good. Let's come back at a quarter to one. That's super.

MS. ECKELS: Quarter to one.

(There was a recess from 12:15 p.m. until 1:16 p.m.)

THE VIDEOGRAPHER: It's 1:16. This is the second tape of the deposition of Dr. Ruckdeschel. We're on the record.

BY MS. ECKELS:

Q. Doctor, we've just returned from a lunch break. And prior to that break, we had begun discussing the general topic of diagnosis and what your opinions are in that area. Do you recall that testimony?

A. Yes, I do.

Q. Okay. I believe you had outlined for me the various diagnostic tools that you and your group typically use in diagnosing lung cancer, as well as -- you told me about some of the typical symptoms. And, as I recall -- correct me if I'm wrong -- you had just told me that the two primary things -- or determinations that are made as a result of the findings from the various diagnostic tools is, one, the histology of the cancer; and, two, the staging of the cancer. Is that correct?

A. That's correct.

Q. Okay. I'm trying to get back to where we left off right before lunch.

A. There was a third piece of that that is, if the patient is an operative candidate or a potential operative candidate or a candidate for aggressive radiation, that there's also the subset of diagnostic information as to whether or not they will tolerate that from a cardiopulmonary point of view, but that's a subset of staging.

Q. I'm not sure I completely understood you. Let me see --

A. Okay.

Q. Are you talking about whether or not they -- a surgical evaluation?

A. If I'm going to operate or have someone operated on, the first question, which is the staging question, is: Is the extent of that tumor such that the surgeon could technically remove it?

The second question, which is quite distinct and is often confused, both in lay and medical circles, is: Are they operable? Will they survive whatever it is we propose to do?

If your pulmonary function or your cardiac function is so bad that removal of half or

one lung leaves you with insufficient lung to breathe, we have not done anything useful, even though we could successfully remove the lung. So that's why I said it's a subset. It's the resectability/operability spectrum.

Q. Thank you. I understand more clearly now.

One of the first determinations that you told me that a physician is able to make after receiving all of the results of diagnostic tests is the histology of the cancer, and we had begun to discuss the various cell types. Do you remember that?

A. Um-hum. Yes, I do.

Q. And I understand your testimony that you believe that cigarette smoking, to some extent, is affiliated or associated with all cell types. Is that correct?

A. It --

MR. SCHLESINGER: Well, Counsel, he didn't quite express it in that terminology, "to some extent." If you ask him the question, I have no problem with it. But if you attempt to interpret what he has to say, I don't think it's reflective of what he said.

BY MS. ECKELS:

Q. I'm not at all trying to put words in your mouth, Doctor.

A. Sure.

Q. What was your opinion or testimony right before lunch, if you could rephrase it again for me --

A. Yeah.

Q. -- regarding the association between lung cancer and the various cell types?

A. Smoking causes all the various types, but in those uncommon-to-rare instances when you have someone who doesn't smoke, ever, and who hasn't had significant environmental exposure, that if you see a cancer in those folks, which you will on occasion, that that is more likely to be an adenocarcinoma or a bronchioalveolar carcinoma, but that smoking itself causes the whole array of them.

And if you took 100 adenocarcinomas, 90 percent of those are going to be due to smoking, and the small proportion of those adenocarcinomas will be those that arose in nonsmokers.

Q. Have you ever treated a lung cancer patient who was a nonsmoker?

A. Yes, I have.

Q. Do you keep any records or statistics at Moffitt regarding what percentage of lung cancer patients are treated there who are not smokers?

A. I don't know that we keep that as a separate and distinct item. I -- I think it's in the tumor registry material. I believe it's -- in my own experience, it's well under 10 percent. And, again, there's an important distinction here. An individual may not have smoked themselves, but if they have been in a workplace where they've had significant constant daily exposure to cigarette smoke over a multi-year period, there are various ways to calculate their exposure.

In addition -- and what may be particularly important, as it is for other cancers -- is a child who is exposed to 20 years or more of his parents smoking heavily in whatever trailer or house they happen to live in.

So if -- you know, there's this issue of how you categorize a nonsmoker, and I would -- and because they -- many people now are so embarrassed by their smoking history, that when we ask someone just -- in fact, we actually, on our intake form, have to ask people, "Are you a smoker?" And I would say half of them say "no." But when you ask the

next question, which, "Were you a smoker," they say "Yes." And then you say, "When did you stop?" "Last week," when their diagnosis was made.

So we do have that information. I'm not sure that we've ever pulled that together, but I would say, you know, from my experience in this, that it's a small percentage.

Q. Would you agree, Doctor, that adenocarcinoma is the cell type that has the smallest statistical relationship to cigarette smoking?

A. No.

Q. What cell type would fall in that category?

A. As I said, the -- smoking causes all of them.

Q. I understand that.

A. Okay.

Q. I understand your testimony in that regard.

MR. SCHLESINGER: Well, let him finish it. Let him finish his answer, Counselor. Please don't cut him off.

A. The -- I would come at it from the other direction, if you'll permit me in here.

So if I -- if I just take the whole world of lung cancers, starting where you started me, they're all associated, and they're all associated to virtually the same degree. It's when I come in the other direction of cancers that arise in nonsmokers, that's where I see a preponderance of adenos and bronchioalveolars, but I -- we still see other types there as well. They're just -- those are even more rare.

Q. Is -- and bear with me on my pronunciation; it's not going to be quite as clear as yours. The bronchioalveolar --

A. Bronchioalveolar.

Q. -- bronchioalveolar -- is that a subtype of adenocarcinoma?

A. Yes. I'm sorry. It is considered such by most investigators. There are some who would claim that it's a distinct form of lung cancer, but it's a semantic issue.

Q. Okay. Do you personally believe that it is a subtype of adenocarcinoma?

A. Yes. And I will -- at any time in here, I would digress to show you, sort of in a diagrammatic fashion, why there are not clear boundaries between the various areas that we see,

but I'll wait for the appropriate moment on that. So you don't say, "Adenocarcinoma, this subset is totally distinct." Bronchioalveolars look at -- look like an adenocarcinoma on many occasions. We frequently see an adenocarcinoma that we say has some features of it; and, as I indicated earlier, many tumors are mixed right from the beginning.

Q. And do you rely, typically, on a pathologist to make that determination as to cell type?

A. Yes.

Q. And what materials do they need in order to make an accurate assessment of cell type?

A. Any number of materials; anything from cytologic specimens, from bronchial washings, fine needle aspirations, which are cytologic. Cytologic means we have loose cells. Histologic means we have a piece of tissue, and those are from biopsy specimens or operative specimens, whichever; any of the above.

Q. In your opinion, are the pathological findings based on histology more reliable than those based on cytology?

A. The vast majority of the time, yes.

Q. You mentioned that the second

determination that is frequently made after all diagnostic results are in is staging. Could you define and explain what staging is?

A. Staging is the -- as I said in lay terms before -- is "Where is it" and "What are the chances that it has spread from the original site of origin?"

So we -- it is based on three components: The size and extent of the tumor, the number and extent of lymph node involvements, and the presence or absence of metastases. And it's "T" for tumor, "N" for nodes, "M" for metastases, the TNM system. And there's a grid that comes from this. The -- and if you take each one of them independently, they have a separate piece of prognostic information. And then when you cross them in the grids, sometimes you get unexpected findings in there.

So, for example, the smaller the tumor, in general, the better you're going to do. The less lymph node involvement, the better you will do. If you have no metastases visible, you'll do better than if you have visible metastases. All those are relatively obvious.

But a small -- very small cancer that has one lymph node positive is biologically much worse

than a huge cancer that either has no lymph nodes positive or has two or three lymph nodes positive, because it speaks to how fast that individual cancer is growing.

So there's a lot of -- this accumulation of events, this summation of all the things that happened to the individual cell, comes up with different answers for how these behave, and they can be very variable.

Now, if you stand back from it and you do thousands of people, there are relentless patterns that we see. But for the individual, they can be quite distinct.

Q. And the determination of TNM has a great bearing on the treatment which is --

A. Absolutely.

Q. -- which is going to be prescribed for a particular patient. Correct?

A. Absolutely.

Q. Why is it important to know where the cancer is?

A. Well, the first issue that I defined for you of resectability -- we would always like to resect a cancer. Everything else we've ever used, whether it's radiation, chemotherapy, immune

therapy, whatever, there is a propensity for the cancer cells to become resistant as part of the changes that they continue to accumulate after they become malignant. But a cancer has never been known to become resistant to being in a pan across the room sitting in formula.

So if we get it out of the body, we're much happier about that. And so, we pay a lot of attention to staging because that tells us whether or not the patient is operable.

Now, for us, in a referral center, we are particularly and peculiarly interested in it because, "A," we need it for clinical research to sort the patients outright. But, "B," we see all the patients who are in the gray zone. And so knowing exactly what their extent of disease is and whether they can survive the operation down to the minutest detail of that is important because we get people who are normally -- I mean, we see two or three people a week who are turned down for surgery elsewhere, who we subsequently go on to operate on because we have a more sophisticated understanding of how to make them operable and what is tolerable for surgery. So that's why the staging is important.

Q. Within your field -- within the field of oncology, is staging universal from hospital to hospital or facility to facility, or is there some variation in how you would determine a staging versus an oncologist in another state or another facility?

A. The staging systems are internationally agreed upon and nationally agreed upon. We have boards and councils, et cetera, that we all accept the staging system. There remain nuances of interpretation of location that people still argue about as the systems undergo change. We and others have argued that the system needs to be changed either by expanding certain categories or contracting others or redefining in certain ways; but, fundamentally, we all agree to the same ones.

Where you run into problems is that people who are more -- who are less well-trained, who have less current experience, will frequently wind up using older staging systems, and they confuse the daylights out of everyone when they report or discuss data in those terms. But the staging systems themselves are universal, if you will.

Q. You mentioned just a moment ago that

there may be some patients that present at one hospital and that they're not -- they're considered inoperable, but yet through the unique and more detailed regime that they're put through at Moffitt, you may learn that they, in fact, are operable. Correct?

A. That's correct.

Q. Would you agree with me that, as compared to most hospitals, a cancer research center, such as Moffitt, is going to do a more detailed evaluation of a cancer patient than the average hospital?

A. It really is dependent on the individual case and specifics, but in these kinds of -- we all see a bell-shaped curve of patients. We tend to see the end of the spectrum where there are complexities and concerns about operability, resectability, curability, tolerability of therapy, et cetera, because that's the nature of a referral center. I mean, if it's a simple, straightforward cancer, a lot of places just take care of it themselves, where it's -- whether it's lung or anything else.

So we tend to see a skewed pattern of that, and so we develop more expertise at that, and it becomes a self-fulfilling issue. So, yes, we do. It doesn't mean that the workup -- the initial part

of the workup is any different at ABC General versus a cancer center.

But when you get to the questionable cases, they could do that workup there, but they're just not as familiar with it and they don't do it every day the way we do. And that holds, I think, for all, all cancer centers.

Q. When a patient is referred to Moffitt, do you accept the workup that was done at -- by the original referring facility, or do you basically start over from square one by taking a history and exam and starting the workup, to use your phrase, over again?

A. Yes. We take a complete history. We ask them -- and do a complete physical examination. We ask them to bring all of the records that they have from their previous institution.

We then review those records -- actually, even before we see the patient -- for timeliness and completeness.

We actually, as part of our daily routine, will present the x-rays, any of the historical material, and the pathology slides at our conference, and look at them together as a group, and decide, "Is this set of x-rays timely enough?"

Have they been done within a time frame that's appropriate, or is there likely to be a change? Are there others that need to be done, or are these fine? Are the films that have come in fine? Is the quality of the film good?"

Same with the pathology. If the pathologist who is present says, "I'm looking at this material and I can make a clear diagnosis from it. I agree with their diagnosis." Or even if he disagrees, but he's clear about it, then we say, "We're done. We have enough material."

If he says, "This doesn't make sense," and I'm looking at something that they're calling this, and I'm not sure it's that and we need to do further tests, then we do further tests, and I -- two to five percent of the time, we have to go back and obtain new tissue because it was not adequate for diagnosis.

So we review everything when it comes back each time, and then we -- it depends on the quality of it. Oftentimes, it's very good and we just use their material.

Q. For purposes of diagnosis, and even for future treatment, how important is it to know the primary site of the cancer?

A. It's always critical to know that.

Q. Why is that?

A. In general, we will treat them differently, depending on where the primary site is. That doesn't mean they'll -- they'll do any better or any worse, but we generally have developed treatments that vary somewhat by the site of origin of a cancer. Some of that's historical; some of it makes good medical sense. Some of it's based on solid research; some on intuition.

So knowing where we think a cancer came from is important to us. The -- and the cancers -- one of the other major elements of managing a patient is understanding the catastrophes that are likely to befall you in the future care of that patient.

So we know that certain cancers -- I'll pick colon cancer or prostate cancer -- tend to spread to the lung or bone, but tend not to spread to brain or other places; whereas, lung cancer will go to brain or spine. And so we're uniquely sensitized to look for it in those places.

So it is -- that's how we would do that, or a colon cancer. If I know someone has that, then every time they get a little bloated, I don't think

they just had too much to eat; I'm worried about bowel obstruction. Whereas, with lung cancer, I'm not worried about bowel obstruction. So it's that kind of picture to understand the primary.

Q. Being that the original or primary site of the cancer is important, what steps do you take -- or your group at Moffitt -- to determine the primary site of the cancer when you see a new patient?

A. The -- we take all the steps that I've previously mentioned in terms of reviewing all the materials.

I would say that 99.9 percent of the time a cancer is either obviously a cancer that arose in the lung, and it has all of those characteristics -- and I can enunciate them in a second if you wish -- or one percent of the time or less we're concerned. We say, "Gee, this clinical pattern doesn't fit. Something isn't -- doesn't gel here." There's a -- either the shape of the tumor or where it has spread to or where it hasn't spread to, et cetera, will click for us.

As an example, we may see a person who presents with coughing up blood, and we would normally say, "Okay. Well, that's a pretty standard

sign of lung cancer," and we'd start looking. And we'd take a biopsy of that, and we would see something in the airway and some small nodules in the chest, but we wouldn't see a big cancer in the lung.

Now, instantaneously, we would say, "This sounds like kidney cancer," which is one of the rare ones that can metastasize to the airway and to the lungs, and so we would expand our search to look for the kidneys in that -- look at the kidneys, and overwhelmingly we find it in those cases.

So we'd track them down, you know, in that fashion, but it is -- it is very uncommon. There are some very clear things about the location, the shape, the tendency to spread into the tissues around them -- we call them spiculations in the tissue -- the spread to the local lymph nodes, the obstruction of airways. I mean, all those things, the order in which things happen, they are so incredibly classical for lung cancer that it is rarely a diagnosis in doubt.

Q. Is it common, Doctor, for a patient to present themselves with a diagnosis of lung cancer and then to later determine that the cancer was metastasized from another organ?

A. I would say that that -- if we see that five or six times a year at the Moffitt, as a whole, for all of our cancers -- let me keep it to our lung area. We see about 500 new patients a year in the thoracic area. And if we see two or three patients in whom that is the issue, that's a big year. I mean, normally it's one -- and, in fact, normally it's never resolved where it came from. You're not quite -- you're just -- even on autopsy, you're still not sure, and that's because people can develop multiple cancers, and so you're not quite sure whether they had an incidental kidney cancer and a lung cancer or one spread to the other, but -- but that is so rare as -- it is extremely uncommon that that's a clinical problem in dealing with people. Usually, it is a sledgehammer on the forehead to let you know that this is lung cancer. It's a very obvious diagnosis.

Q. Okay. I'm just a little confused now between the rare and the common. Did you just say that it is common to never know exactly where the cancer came from?

MR. SCHLESINGER: No. He didn't say that, Counselor.

Q. Did I misunderstand you?

A. Yes.

Q. Please state it again.

MR. SCHLESINGER: Did you misconstrue that?

Q. Apparently, I misunderstood you, Doctor.

MR. SCHLESINGER: Yeah.

Q. Would you -- regarding the incidence where you do know the exact primary site and origin of the cancer versus those percentage of the incidents where you don't ever know where the cancer originated, how does that play out?

A. Okay. There are -- now, in the area of lung cancer, again, separating this out from cancer in general, okay? -- when we're dealing with bowel and other sites, there are frequently cancers we're not quite sure where they came from. Okay?

Q. Okay.

A. When we're dealing with metastases to the lung or to lymph nodes or to bone, we occasionally -- two to three or four percent of the time -- don't know where they came from and may never find it, even at autopsy.

With lung cancer, on the other hand, 99.9 percent of the time we're absolutely sure it came from the lung. Very rarely -- extremely

rarely, we have difficulty trying to sort out whether what we're seeing in the lung is something that arose in the lung or came from somewhere else.

Q. Would you think that that is true for all facilities, or is that perhaps uniquely true for Moffitt because of the type of referral facility that Moffitt is?

A. I think that the percentages may change to -- from a tenth of a percent to one or two percent elsewhere, and there's a big difference between what you see and you think the first day you see a patient and what the workup ultimately shows.

So, yes, the first day you look and you say, "Gee, I'm not sure where this is." That doesn't mean that that's your opinion forever.

So I think in the vast majority of institutions where you have competent diagnoses, good internists, good surgeons, good pathologists, good radiologists, 98 percent of the time it's very clear from day one.

Q. Do you know what the data statistically is on lung cancer, of original primary site lung cancer versus metastases to the lung?

A. Yes.

Q. What -- can you tell me what that is?

A. Well, again, it depends on -- on several things. If you -- I know -- I can relate to you in gory detail all the survival data in lung cancer, and that's -- we can do that at any time, but -- and that's stage-related. It used to be more histology-related, but that's hardly -- it's really almost not an issue anymore. It's mostly stage-related.

The -- cancers that come from elsewhere; it depends on what that cancer is and what its growth rate is, so --

Q. Let me stop you right there. I'm sorry. When you say "what that cancer is," are you referring to cell type?

A. Yes.

Q. Okay. Thank you.

MR. SCHLESINGER: Counsel, don't do this. Please don't interrupt the witness when he's in the midst of an answer.

MS. ECKELS: I'm just clarifying the testimony.

MR. SCHLESINGER: You can clarify it when he has finished his answer.

A. The cancers that arise elsewhere and spread to the lung, that are primary elsewhere, have

a period of what we call disease-free interval that impacts on them and is related to their growth rate.

So, for example, if I resected a breast or a colon cancer from you or someone you knew, and I did that six months ago, and you present to my office today with spread to the lung, then I say, "A," I knew that those cells had to have been there six months ago, and that that's a pretty rapidly growing cancer, because it's gone from nothing that I can see to something that I can see, which is going from a million or two to a couple of gazillion cells in a relatively short period of time. It's doubled quickly.

And so I say, "Gee, that is a very bad prognostic sign." In that particular colon cancer, that patient is going to die very quickly unless we're very lucky with chemotherapy.

Other colon cancers that sit for three and four years before it shows up in the lungs -- again, I say, "Yes. Those cells were there in the lungs at the time of the surgery, even though we couldn't see them. But it's taken them three or four years to grow up to a point where we can see them," and that then determines what we do for therapy. When they're very slow-growing like that,

we'll go in and try to resect them from the lung if they're within a reasonable number.

If there's a whole slew of them, or if they've shown up within the first year after the previous surgery, we make the presumption that this is a biologically bad cancer. So, again, there's not a fixed answer to "one is worse; one is better."

So, in point of fact, you can have a metastatic cancer from elsewhere that has a wonderful prognosis because you can cure them because of that issue of very slow growth. You can go in and resect them. It's uncommon, but you can do that. And the lung cancers can run their normal spectrum. They're a -- they're a different kettle of fish and it's an -- something that's individualized really with each patient and their cancer.

Q. And perhaps I didn't word my question adequately, Doctor. What I was asking you, and what I'm going to try to ask you now is: From the overall number of lung cancer cases in the U.S., are you familiar with any statistical data or studies which breaks down the percentage of those cases which are primary lung cancer cases versus those which are metastatic cancer to the lungs?

A. There is no -- it's not a way we would normally -- I mean, it's like talking about the menu in a restaurant and the things you can buy on a car. I mean, they're usually not listed in the same context. So that would have to be experiential, just from what I've seen at various institutions, and I think I gave you those figures already, but I don't think anybody collects the data in that fashion.

Q. Okay. And the figure you're referring to is the 99.9 percent figure you gave me earlier? Is that what you're referring to?

A. Correct. Yes.

Q. Are there cancers from certain organ systems that are more likely to metastasize to the lung than others?

A. Yes.

Q. What would those be?

A. There are two things that determine that, sort of where the cancer arises and what -- if you will, what we call capillary filters. Can I sketch something here for you, or is that going to mess up the videotaping? It's a simple --

Q. I'll -- I have no objection. I'll let your counsel decide whether he has a problem with

it.

A. Is that all right?

MR. SCHLESINGER: I'm not his counsel.

A. If I have some --

MR. SCHLESINGER: I'm just a lawyer here.

A. If I have a cancer that's down in the bowel, the usual source of that is the -- is it gets into the bloodstream and it heads back to the liver, at that point the vein breaks down into capillaries, and then comes back together as a vein; and then it gets to the heart, and then it is shipped to the lungs where it, again, breaks down into very, very tiny blood vessels. Again, these are all veins coming this way with -- on the other side, those capillaries re-collect into arteries, and then the blood is pumped through the body.

So if a cancer goes to the liver first, which bowel cancers tend to do so, because their blood drainage goes that way, then they tend to spread to the liver, because that's the first filter that they come upon.

Cancers that -- that don't do that, that tend to arise in bone or in soft tissue and other places, the first thing they tend to see, because their blood supply comes in here past the liver, is

the first filter they see is the lungs, and so the tendency is for them to spread to the lungs as the first site.

So the first thing is this issue of the first filter, and then there are several issues related to what we call tissue specificity. It seems clear; it's not fully defined yet at the basic science level, but it is well-defined clinically, and that's what clinical experience is -- that certain cancers tend to grow better in certain organs.

For example, prostate cancer and breast cancer, almost invariably, spread to bone.

What it is about the bone that -- the environment of bone that a hormonally sensitive tumor like that is -- that makes it spread there is less clear. There are others, perhaps, who know that better than I do. But there's that clear tissue specificity for bone.

So if I see a man and he's got bone pain -- he's aching. Somebody shows me a bone scan with 30 different sites lit up, prostate cancer comes to my mind instantly. That's the first thing.

If I see a woman with that bone scan, it's breast cancer that I come to.

And there are, indeed, some cancers that seem to have a predilection for spreading to lung as the first site to do that. Head and neck cancers -- for example, larynx, throat -- tend to spread to lung as the first site.

Sarcomas seem to have a predilection for spreading to lung and staying in that particular organ.

Q. I'm sorry. Are you finished?

A. Yes.

Q. I wasn't writing as quickly as you were speaking. You said, "Head and neck had a strong likelihood of" --

A. And sarcoma.

Q. And sarcomas. And did you say -- was there another one in the middle? Was it larynx?

A. Larynx and throat are all head and neck cancers.

Q. Okay. Was there -- did I miss one other than head, neck and the sarcoma? Okay.

A. No. I don't -- this is --

MR. SCHLESINGER: You can briefly hold it up, just so the -- can you get that?

THE VIDEOGRAPHER: I'm getting it. Just a moment.

MS. ECKELS: If you feel more comfortable attaching it as an exhibit, that's fine.

MR. SCHLESINGER: It's not necessary.

THE VIDEOGRAPHER: Okay.

THE WITNESS: Okay?

THE VIDEOGRAPHER: Thank you.

THE WITNESS: It's the teacher in me. I'm used to drawing diagrams of how things work, so --

MS. ECKELS: And that's very helpful. I appreciate it.

BY MS. ECKELS:

Q. Would it be correct to say, Doctor, that the likelihood, then, of cancer from one organ system metastasizing to the lung -- one factor in that process is the transportation system of the blood, the way in which it flows?

A. That's correct.

Q. The second factor is the various organs that it -- that transportation system interacts with; and, as you use the phrase, filters?

A. Yes.

Q. Okay.

A. There's also an issue of how much blood gets to each organ. Some organs have a very high

blood flow; brain, kidneys, for example. Others have a much slower blood flow, so there's statistical chances based on how much blood goes to a place as to whether something that's blood-borne will get there or not.

Q. You mentioned that you believe there's a strong likelihood that you will frequently see breast cancer metastasize to the bone.

A. That's correct.

Q. Have you ever seen breast cancer metastasize to the lung?

A. Yes.

Q. Have you ever seen bladder cancer metastasize to the lung?

A. Yes. Before we go down that, I've seen virtually every cancer metastasize to the lung at one point in its course, okay? So even though that colon cancer has a propensity to go to the liver, where other cancers have a propensity to go to bone or someplace else, they will, with the -- well, I can't say that. Even brain tumors, I've seen one that has spread. That's about as rare a thing as you'll ever see. But virtually every other cancer can spread to lung.

But the pattern of that spread and what

it looks like clinically and the obvious history of either an active cancer elsewhere or history of a previously resected cancer in the area sets it off -- makes it relatively obvious whether we're dealing with metastatic disease or not. Is it always that way? No. I mean, there's always a few oddballs that you can't figure out, but the vast majority of the time.

Q. You just mentioned time factor --

A. Yes.

Q. -- between a prior cancer being resected and a later diagnosis of lung cancer.

A. Yes.

Q. Is there an accepted time frame within which you would expect a cancer that has been resected or treated in another organ system to metastasize to the lung?

A. Yes. It's highly variable, however, and it's -- and it's related to, you know, this process of going from one cell to two cells to four cells to eight cells to one billion to two billion to four billion. It's the interval of time in between there that's important. That's very variable between cancers. It tends to coalesce into a little narrower package of times for various types of

cancer, but there's still broad diversity among cancers, even within the same cell type, in what's called doubling time, the time one goes to two, two to four, et cetera, and how that process works.

So there are some cancers, primarily lung among them, leukemias, relatively rapidly growing cancers -- that if there's no evidence of it after three, four, five years -- the chances that it had spread and is going to come back are extremely low, and the risk is more of a second cancer arising.

On the other hand, breast cancer, colon cancer, some of the slower-growing cancers -- clinical trials in breast cancer often have to last 10 or 20 years of followup because you -- I've had women 27 years after their breast was removed show up with bone metastases from what was a dormant, very, very slowly growing breast cancer, which has now, obviously, undergone another mutation and starting to grow more rapidly. So we just know that clinically. We know the ones that are capable of going very slow.

So a breast cancer patient, I say, "Yep, things look great. We're five years out. We're not totally out of the woods yet." Whereas, with a lung

cancer patient or leukemic, I'd say, "We're out of the woods."

Q. In your experience, Doctor, when a lung cancer patient presents themselves, in most facilities -- and I don't want to confine this just to Moffitt because of your unique research evaluation -- and --

A. Excuse me. That's a clinical evaluation, not a research evaluation we do.

Q. I'm sorry. Thank you for the correction.

A. Yeah.

Q. In your experience, in dealing with medical facilities, generally, when a lung cancer patient presents themselves and it is determined that the staging is advanced, do most clinicians determine whether or not that cancer was a primary or a metastasis?

A. Yes.

Q. Does it make a difference in the course of treatment?

A. It often does, yes. In fact -- let me clarify that. Virtually all of the time it makes a difference. It makes a difference in what they choose to treat with. It may not make a bit of difference in terms of what the outcome is.

Q. How does it affect the treatment? What varies the treatment based on primary versus metastasis?

A. If I have a metastasis to the lung that came, for example, from the colon, there are certain drugs that we use for colon cancer that are marginally to modestly effective that have absolutely no benefit whatever in lung cancer, and vice versa.

And so if I have a colon cancer that metastasizes to lung and I am either fooled or lazy enough not to do the evaluation, and assume that it's a lung cancer and I give it lung cancer therapy, I have not given them effective treatment for their colon cancer. If I do the opposite, I give them colon cancer therapy; I've not given them active -- or appropriate treatment for their lung cancer, and that's particularly important in areas like breast cancer where we have this one whole option of very, very non-toxic hormonal therapy.

So for me to have a mass in the lung and a woman who has had a prior breast cancer and not be very certain about whether that's a metastasis or a primary -- again, that's not usually a problem. But to not be certain about that -- for any physician

not to be certain about that, when one whole group -- a quarter of them are going to wind up on hormonal treatment, which is extremely benign and likely to last thoroughly -- you know, a thoroughly good response for many years. I mean, that's -- that's not in the patient's best interest, so --

Yeah, most people are very, very -- first of all, it's obvious clinically; it's so overwhelmingly. And then the ones where it's less obvious, they do that.

There are a set of times when you see what is obviously -- and this may be the issue of the carcinoma of unknown primary that people like to talk about and get confused when dealing with this.

If I see a cancer that is obviously metastatic to lung, bone, lymph glands, in the neck, wherever else, but it clearly came from someplace -- it didn't arise in the lung; I don't see it there. I look in the throat; I don't see it there.

I do some very basic tests, and I don't find it.

Then there's a whole debate in the literature about whether you should bother to do more tests to figure out or whether it doesn't really matter at that point in time. But those

cancers are obviously metastatic on -- and that clinically distinguishing them from lung cancer is not, in my experience, a significant problem.

Q. Is it also correct that the pathology will frequently indicate whether or not it's primary or metastatic?

A. The pathology will suggest at times. It is not -- as I said, lung cancer can present in many different ways histologically. It has a whole spectrum of changes that occur. And so that's part of what we do in conferences. We say, "Does the pattern that we see under the microscope match what we're seeing clinically?" And if there's some disagreement between them or a suggestion of disagreement, we track it down.

Q. You've discussed for me the various diagnostic tools that you use and what determinations are made from those, and I believe one of the things you mentioned is that a complete history is taken. Correct?

A. That's correct.

Q. Why is that important?

A. The history has several elements to it. One is, as we build a database about that patient, understanding, "What are the unique aspects of this

patient? Do they have allergies? Do they have other problems that are going to impact on their therapy?" in any given direction. "Have they had something before? Is there something I need to know about that's going to change how I think about their therapy?" And I think that that's a compulsion among us, to do that accurately in a consulting sense.

I need to know, for example, that someone has been a heavy smoker because not only am I -- I don't use it to chastise them, but not only do I know that was the cause of what they have, but I know that that's going to have impacted their pulmonary function and their cardiac function and that that may seriously limit how I can treat them.

And so, the minute I know that they've been a three-pack-a-day smoker for 20, 25 years, as opposed to a pack a day for 15 years, and put that together with their age, I'm going to say, you know -- already, even as I'm taking that history and listening to it -- "Okay. I need these extra tests. I'm going to have to make sure about his breathing function, about his cardiac function, if we're going to do any surgery on this patient." So, I mean, it helps you distinguish that as you go along.

You're also looking for, as I mentioned earlier, what's called "catastrophe management." And whether it's at time of diagnosis or later on, there are certain things, like back pain or confusion or headaches or double vision, that tip you off that a medical catastrophe is about to happen, whether it's spinal cord compression and paralysis or whether it's seizures and coma -- developing a coma from brain metastasis.

You need to listen very carefully in the history and sort them out, so that no matter whether you can lengthen their life one day or not, every day of that life is spent walking, talking, interacting with family and the like.

Q. You -- a couple of times during the course of your deposition now, you've mentioned pulmonary function tests and things of that nature. Perhaps one thing I didn't ask you about earlier is: Do you consider yourself an expert in the area of pulmonary function tests and pulmonology?

A. Yes, with the provisos I've given before: Although I'm not board certified in pulmonology, I am a fellow in the American College of Chest Physicians through my expertise in lung cancer, and how that overlaps -- you cannot do lung cancer

without becoming an expert in pulmonary medicine, because you have to distinguish those things all the time, and you work with pulmonary function tests every day.

What I don't do are the critical care issues. It's the other half, the ICU management, ventilator management of people, and some of the infections, but -- so, yes. And I'm prepared to testify about pulmonary functions, what extent are appropriate, inappropriate for various types of therapy.

Q. And in your experience, Doctor, have you seen patients that have been diagnosed not only with lung cancer but also with COPD or other pulmonary diseases?

A. Yes.

Q. Okay. And how do those two interact or affect each other?

A. They almost always run together. People who smoke heavily will, a proportion of the time, develop lung cancer. A far greater proportion of the time, they will develop what we call chronic obstructive pulmonary disease, which has many manifestations, from bronchitis through emphysema; and, in fact, may have no clinical manifestations.

They may not be short of breath. But if you actually measure what their capacity, what their reserve is, they've lost a significant amount of that capacity and reserve through their smoking behavior.

Q. And those percentage of people who have a pulmonary disease and do not have lung cancer, you don't treat those kind of patients yourself, do you?

A. On occasion, people who have had a prior cancer, who do have chronic obstructive pulmonary disease, who -- that gets worse in the course of them seeing me in follow-up or whatever, yes, I will frequently manage those patients.

And, of course, in the area of lung cancer, those patients frequently have exacerbations of their chronic pulmonary disease.

And when I originally talked about what I did in terms of being the primary care specialist for a patient, managing their chronic obstructive pulmonary disease with all of its components is something that I do on a regular basis, and have for many years.

Q. Do you treat patients who have pulmonary diseases without a history of lung cancer? In other words, do you typically treat a patient with

emphysema, asthma, things of that nature, that don't have a cancer component and never have had one?

A. Not typically, but frequently. In other words, the patients that I see who had a prior breast cancer or something else, who I'm seeing as -- either because I've picked them up when I'm on the inpatient service or whether they've been referred to me by -- on a VIP basis, or whatever -- a friend of somebody, friend of Mr. Moffitt's or anybody else. If I'm seeing that patient and they happen to have chronic obstructive pulmonary disease, I treat it in that setting. I don't usually refer those patients on.

Q. Are you prepared, and do you intend to offer expert testimony regarding the association between cigarette smoking and pulmonary diseases which do not have a cancer component?

A. To the extent that I -- that I know that smoking causes COPD, that there are only a handful of allergic and infectious problems that will cause that picture, that the overwhelming majority of it is due to smoking, that the evidence for that is the same compilation of epidemiologic and clinical and research evidence that there is for smoking, yes, I'm prepared to speak to that.

Q. We were talking about the history that you typically want to take or would take in a patient who presents with lung cancer. Is there a standard questionnaire that's used at Moffitt?

A. Yes, there is.

Q. I'm sure it's lengthy and has a lot of questions on it, but can you cover for me, Doctor, the basic subheadings or categories of --

A. Yes, I can.

Q. -- of questions that are covered on that questionnaire?

A. The first thing that we have is a section that asks the patient to describe in their own words what happened, and it's basically a blank page like this with lines on it, and that allows the patient to write down, "I was diagnosed with X" or to write out that long history they like to about this and that test and where they went and which doctor did this and where they did that and that they thought it was due to whatever and -- they get to put their whole story down, but it's in their words, okay?

Then we ask them a general sense of, "Before all this started, how did you feel? Excellent, good, fair, poor." And "How do you feel now?" Sort of get a sense of what's happened to

them.

The next piece we ask -- unique now to a cancer center -- is "Have you had any prior treatment for this cancer?" Because that influences what we can do. That's a separate page.

We then turn to a next page, which is "Family History," where we ask: What other diseases have been in their family; what other family members they have; are they alive or dead? Do they have -- if they're dead, what did they die of? If they're alive, do they have any significant illnesses? -- again, looking for patterns within families of certain diseases or other things we need to watch out for.

The next page is what we call "Social History," and on that page is a section at the top of the page on their habits. Those include a detailed smoking history, a history of alcohol consumption and history of drug usage.

The second half of that page are -- is a series of what we call "social supports." It asks the patient whether or not they have certain characteristics that we associate with the need for psychosocial counseling and intervention. Do they live alone? Do they have someone helping them? Are

they having problems with transportation, et cetera, et cetera. Anytime they check one, we know that patient is going to have trouble with therapy.

Are you comfortable your insurance will cover this, et cetera. So we ask those questions, and that tells us -- of the 15 patients we're seeing today, only two or three are going to have hits, are going to have positive findings there. And that's who the social worker sees. She can't see all 15 of them, so we focus on the people that need that.

Then we turn to their employment history. We ask them where they've worked, what kind of jobs they've had, whether they've had particular industrial exposures of any kind, any kind of occupational or workplace exposure, anything unusual. If they give us a hint of that, then we'll pursue that in more detail.

And then there's a several-page section on what we call a "Review of Systems," and we ask salient points of specific symptoms for every organ system in the body, hoping to isolate one of two things: A) A history of something that's happened before; or, secondly, whether or not they have any of the potentials for catastrophic illness that they themselves have not put together. The patient with

brain metastasis may think their headache or their trouble with reading is just a change in their eyeglass prescription. But when I see headache or double-vision on that sheet, I'm off ordering something looking for a spread to the brain, because I know that pattern. They may not know it as someone who is medically naive.

That's the form. And then the last page is: What questions do you have? What things would you like us to answer for you? It's a good form.

Q. Family history. In taking family history, and in your experience in oncology, is there a pattern of lung cancer running in families?

A. Yes, I believe there is. We're starting to see pretty clear evidence of that now. That comes from several sources.

The history, with all of these cancers, has been the degree to which we can find it running in families, first; and then, secondarily, identify the specific gene that's abnormal.

Now, there are some cancers where the relationship to a family history is overwhelming. Breast cancer in women, for example. If your sister and your mother have had breast cancer, you're a walking time bomb for that. And we can actually now

get down to the specific gene for that in some percentage of women with breast cancer.

In lung cancer, that data has been less clear. We see, however, that there's a two- to threefold risk, that if a first-degree relative who's been a smoker has had a prior lung cancer, that you yourself have a higher risk than others who don't -- or other smokers who don't have that family history. And that goes into that multifactorial aspect. The sum of all these things that happen to someone results in an individual risk pattern for an individual.

So if I have a family history of heavy smokers, all of whom get lung cancer, and I've had two or three deaths from that in the family -- and that's not uncommon; I see that frequently in my practice -- people sort of sitting there, going (indicating) -- making these gestures, you know, "I wish I had figured that out earlier in my life" -- that if I see that in a family, and I've got a smoker in front of me with a mass on chest x-ray, it's not hard to extend.

But when I calculate risk for an individual who doesn't have cancer -- for any one of us, for example -- it's that combination of whatever

their genetic risk is -- and that's, in itself, multi-factorial -- with whether or not they smoke.

So the person who has the genetic risk who never smokes has a risk of lung cancer that's down where the average person is, and so we have to -- you have to sum those two things -- those two -- 50 different things that add up to an individual's risk of developing lung cancer, and family background is one of those. It's not as strong as it is for other cancers, but it is clearly present.

Q. Is there a generally-accepted percentage risk that is associated with a strong family history of lung cancer and -- in case I'm not asking this well -- in other words, do you generally know that a person with a strong family history of lung cancer has a 10 percent increased risk or a 20 percent increased risk? Is there a statistic associated with that?

A. Two- to threefold, if they're smokers.

Q. What if they're not but have a strong history of it in their family?

A. Then there doesn't appear to be an increased risk.

Q. Not to jump around -- I'll come back to the genetic and the history for just a moment, but

another question just popped in my mind. We were talking a little while ago about pathology, determining primary site versus metastases.

Is the use of immunohistochemical testing a method by which you can determine 100 percent of the time the primary site of the cancer?

A. No.

Q. Okay. What is the percentage of reliability, if you will, for using immunohistochemical testing on a tissue sample to determine original site of cancer?

A. It's actually relatively low.

Q. Really?

A. Yes. The -- we would think that's the case, that it should be very high and very specific; but, in fact, it turns out it's not, and it turns out that there's a great deal of overlap in tissues.

The fundamental problem is that cancer is not something foreign. It is a part of the -- your -- the individual that's run amuck. And so the cancer cell has carried with it -- even though it's growing wildly, those controls are lacking -- it still carries with it all that information that it had as a normal cell. It's not like measles or mumps or tuberculosis, which carry unique pieces of

information that the body can recognize.

So, yes, we use immunohistochemistry all the time; and, yes, it is very helpful in distinguishing some forms of cancer, but there's a great deal of overlap. In fact, you'll see a couple of my papers relating to the use of immunohistochemical markers in lung cancer, and both of those papers show that it is not helpful to run a battery of immunohistochemical markers; that it does not distinguish small cell from non-small cell or good prognosis from bad prognosis. So that's where my opinion comes from on that.

Q. Is the use of immunohistochemical testing more reliable on certain types of cancers as opposed to others?

A. It's more reliable in answering certain types of questions than it is in others.

Q. And what types of questions would those be?

A. Yes. And I wasn't being difficult. I knew you were going to ask the types.

Q. I knew you weren't.

A. I think that there are certain questions about whether or not we see the presence or absence of certain things. Mucin, for example, or carcino-

embryonic antigen are two compounds that if we see them, we know, then, that that cancer is not a mesothelioma.

If we see certain other ones, we know that it's more likely to be a sarcoma than something else. But the number of times where that information is what tips the balance in a diagnosis versus this group that -- where it has no -- I mean, if we get it, it's nice, and it's there, and it's confirmatory, but it didn't help us with the answer; occasionally sorting out whether an adenocarcinoma came from the ovary or not. It's helpful; but even there, lung cancer is -- you know, the specific antigen for ovarian cancer is CA-125. Well, the second place that makes that, most commonly, is lung cancer. So it doesn't really help you to do that.

CEA can be made in the bowel; it can be made in the lung; it can be made in the breast. It doesn't help you. So the specificity of using those tests is not that great, and I -- we use it -- maybe five or ten percent of patients' immunohistochemistry actually helps us sort out a particular question, but no more than that. We may get it on 70 percent of patients, but that doesn't mean it helps us.

Q. Thank you. Back to the subjects we were discussing on history, I want to make sure I understood something that you said a few minutes ago. We were talking about the strong family history of lung cancer for a non-smoker -- or in a particular patient who's a non-smoker.

Is it your testimony that that individual has no increased risk of contracting lung cancer?

A. If I see someone who has -- one of their parents, for example, was a smoker and had lung cancer from that, okay, and now that person comes to me in a social situation, or whatever, and I don't think they have cancer. I mean, they're asking me, "What's my risk?" Okay.

The first thing I ask is: Do they smoke? If they smoke, I'll say, "I'm concerned about your risk. I think it's two or three times higher than even other smokers whose risk is 30 or 40 times what a non-smoker's is."

But if you are a non-smoker, and have been, and were not exposed to your parents smoking in a confined space for many, many years, then you probably have no increased risk over anybody else walking around who has been a non-smoker. There's always a background noise of cancers that will arise

in true non-smokers, lung cancers that will arise in true non-smokers. That's what we used to see before the 1900s, those little background noises, an uncommon but described cancer. So that's what I would tell them.

Q. Are you familiar, Doctor, with any current studies or data indicating that the incidence of lung cancer is on the increase; yet, the number of adults or individuals who are consumers of tobacco products is decreasing?

MR. SCHLESINGER: I'm going to object to that. If you have data along those lines, give it to him and ask him if he agrees with it. A supposition as far as data is concerned perforces that there is such data and, therefore, I object to it.

BY MS. ECKELS:

Q. You can still answer the question, Doctor. I'm asking: Are you familiar with or are you aware of any such data?

A. I am familiar with data, and before -- before I answer that, I need to explain what that data is --

Q. Sure.

A. -- because, in point of fact, your

question made a supposition about it that's inaccurate. The -- or that I think is inaccurate.

The data as we have it is that in men, for some years now, the rate of smoking has diminished; and that, for the first time, we are now beginning to see a diminishment in the number of deaths due to lung cancer, both the incidence of lung cancer and the number of deaths due to lung cancer in men.

Women who started smoking long after men didn't start their -- men started their heavy smoking history around World War I. Women didn't start until around World War II.

Women, on the other hand, are still increasing, both in -- now, the number of smokers, adult women, has leveled off some, but the number of cases of lung cancer and the death rates from it continues to rise in epidemic proportions.

The place where there is a dramatic increase in smoking behaviors is among adolescents, particularly adolescent females; and in particularly -- felt very strongly to be related to the advertising campaigns for that. And so what we see are -- it depends on what piece of the data you want to look at. Okay? If you want to look at men, yep,

rates are going down. But if you want to say, overall, are more people smoking? No. Smoking is down all over, but not in certain groups.

So you have to -- you have to -- we have to take which part of that data we want to look at. All the data is there. And what it shows is, if you smoke for a prolonged period of time, you get lung cancer. And if you, as a group -- whether that's, you know, the adolescent females of today who are all taking up smoking -- 20, 25 years from now, we're going to see an epidemic of them getting lung cancer, as night follows day.

The same as the -- women started smoking. They got emancipated from smoking restrictions around World War II. Bam, up went their smoking rates, and you can follow it in any country, any country where they -- where there's -- where the smoking behaviors were truncated by war or famine or economic conditions, and they suddenly change and the smoking rates go up. Just wait 20, 25 years, and there it is.

The Japanese, for example, had a much -- were not heavy smokers before World War II. With the American occupation, they became significant smokers, and now we're just starting to see an

epidemic of lung cancer in Japan as well.

Q. Do you attribute any of the statistics showing a decrease in deaths due to lung cancer due to the fact that detection and treatment has improved?

A. I think a small portion of that is -- as I have said in several editorials, is due to improved treatment.

Our detection, I don't think, is particularly improved yet, although I'm involved and chair several studies in that area. I don't think we've made major -- major advances in our ability to detect it early. Hopefully, that will change in the next couple of years, but not to date.

Our treatment is better. We've probably improved treatment outcome by four to five or six percent maximum over the last 20 years, but it seems very clear that the -- the decreased incidence and death rate from lung cancer is due to the fact that somewhere in the '60s and '70s, men, in particular -- in fact, the first group as a whole were white male British physicians who, almost to a person, stopped smoking -- almost as a group. It was a phenomenal sociologic change. And starting with, oftentimes, physicians, but going right through the

male population, the dramatic decrease in smoking among adult males has been followed by, as we would hope and expect, finally, a leveling-off and now a decrease in the incidence and death rates due to lung cancer.

Q. I'm going to object to the last part of your answer as being nonresponsive to the question.

MR. SCHLESINGER: You may not have liked it, Counsel, but it was --

MS. ECKELS: It was nonresponsive.

MR. SCHLESINGER: -- completely and totally responsive to the question.

MS. ECKELS: My objection stands. I object to it as nonresponsive to the question.

MR. SCHLESINGER: Overruled.

MS. ECKELS: Well, fortunately, you're not the judge.

BY MS. ECKELS:

Q. In talking about family history, what other factors are you interested in determining other than the incidence of lung cancer within the family?

A. Obviously, I'm looking at other -- whether they have other cancers. I'm looking, do they have a history of unusual lung disease, kidney

disease, liver disease, something else that might impact on my ability to treat them.

People with -- one of my practices used to be in Saranac Lake, which was the place they sent all the tuberculosis patients from New York City. It was a huge TB sanitarium up there, and so we would frequently see people who had been treated for TB 30, 40, 50 years ago who had been smokers. They now came in with lung cancer, and lung cancer frequently obstructs airways and causes changes out further in the lung. And I can't tell that from tuberculosis or infection due to the lung cancer. And some of these people would have reactivated their TB, so I'm going to ask. If they've had a TB exposure, that's just one more thing I keep in mind as I go down the litany of things I'm looking for in a patient.

If they've got a history of polycystic kidney disease and I'm thinking about treating them with chemotherapy that includes a platinum derivative that's going to put a whack on their kidneys, I want to know that before I start treating that patient. So those -- I mean, those are just the routines that we would ask.

Q. Is there a section on the history form

for them to either check off or list all of the various diseases that they're aware of within their family tree?

A. Um-hum. Yes.

Q. Does that include diabetes?

A. Yes.

Q. Does that include elevated cholesterol?

A. Yes. I'm sorry. It includes heart disease. It doesn't specific elevated cholesterol.

Q. Have you done any type of a comparison, or are you aware of any of the differences in the family histories of those Medicaid patients that you have treated versus the non-Medicaid?

A. No. I think the -- there are differences by socioeconomic status in family histories. Frequently those are related to access to early medical care. We see them whether they're Medicaid patients or non-Medicaid patients. But aside from that issue -- there are also differences by racial or ethnic subgrouping; and depending on, in a particular city, what those may be, there may be differences there, but they -- they are not based on their Medicaid status.

Q. And understanding that you see them whether they are or are not a Medicaid patient, what

socioeconomic differences have you noticed or are you aware of between the Medicaid patients that you have treated and the non-Medicaid patients you've treated?

A. Very minimal differences. I think the slight difference is with respect to when they seek care, their access to care, and in -- you know, in New York and Florida, you have two states that really have fairly decent Medicaid regulations. So that provision of early symptoms -- care for early symptoms is available, so you don't see some of those discrepancies that have occurred in other areas. So I would say, really, they're fairly minimal, and I can't -- I usually don't distinguish them. I often don't know who has that. I can tell, at either end of the spectrum, the person who comes in extremely well-dressed in a Chanel suit versus the person who comes in, you know, off the street. I can tell them apart, and I can suggest this one's probably on Medicaid and this one isn't, but that's a -- but in between, it's very hard to distinguish, either clinically or socially.

Q. Is it important, though, to -- or can it be important, though, the difference in the access to health care they've had going back as far as

childhood?

A. In general, no. And the reason for that is that this is a -- this is a cancer that we cannot diagnose early, despite our best efforts; and, therefore, whether you have absolutely spectacular access to health care from childhood on, and get all manner of tests right through that, there's, to date, no good evidence that that will catch you earlier. The early cancers we catch are usually flukes, somebody coming in for a cataract operation who gets a chest x-ray and it's -- it's abnormal. But just routinely doing the population, there are huge studies to show that it has not been beneficial in early detection.

Q. It is -- is it important to know a fair amount about the childhood in terms of childhood exposures and childhood diseases and how that may later relate to cancer being diagnosed in the adult?

A. Well, it is and it isn't. There are certain areas where it is important, and I -- and lung cancer, for example, I do not look to that as a primary piece. I look to that as a secondary piece.

So if I'm sitting here and a person tells me that, you know, "I've been told by my primary care physician that I have lung cancer and he sent

me here to see you, but I've never been a smoker, and I don't understand this," then one of the things I will pursue is environmental tobacco smoke and whether or not they had heavy exposure as a child.

If someone says to me, "I've smoked cigarettes for 40 years at two packs a day," I don't much care what their exposure from their parents was, so I don't really pursue that aspect of it.

On the other hand, a cancer like melanoma, I'm primarily concerned, if I have a skin lesion there, because it is -- it is the history of childhood severe sunburns that leads to adult melanomas.

And so I want to know, did this -- did you, as a child, have frequent severe sunburns? And that becomes a very important piece of information in that. Those are two ends of that spectrum.

Q. What other differences do you -- have you ever noticed between family history of a Medicaid and a non-Medicaid patient, if any?

A. None in particular.

MR. SCHLESINGER: That presupposes that he's noticed some in the past. He hasn't told you that he noticed any.

MS. ECKELS: Yeah, he just did. He just

told me about one.

MR. SCHLESINGER: Well --

BY MS. ECKELS:

Q. Going from family history to social -- to the social history, have you noticed any differences between the social history taken from a Medicaid patient and a non-Medicaid patient?

A. Well, social history includes job, smoking, alcohol and drugs. I mean, those are the things we're basically looking for in those -- in those areas. And, obviously, the job history of someone who is on Medicaid is frequently different, again, at the ends of the spectrum.

But in the middle of the spectrum, there are plenty of people who are just off of the Medicaid range who hold the same jobs with the same exposures; pretty hard to distinguish.

Someone who's a captain of an industry is unlikely to be on Medicaid, I mean, at those extremes. That's relatively easily -- so, again, not in particular.

Q. You mentioned to me that a separate category that you explore on the history form is exposures, occupational exposures, which may relate to social history --

A. Yes.

Q. -- but you mentioned it as a separate category.

A. Yes.

Q. What differences have you noticed there between the Medicaid and non-Medicaid patient?

A. Again, no particular difference in there. Again, at the far extreme, there are people who have been in high-level, white-collar jobs their whole life, and there aren't too many Medicaid patients that have been there. But in between all those other industrial jobs that people have held through their lives, there is no difference between Medicaid and non-Medicaid.

Q. In discussing and in covering your opinions regarding the diagnosis of cancer, we've discussed the diagnostic tools, what can be determined from them, the history that's taken, the various staging of cancer. What other opinions do you have, Doctor, related to the diagnosis of lung cancer as it is associated with cigarette smoking?

A. Well, I -- and I thought you were just going to ask about this one, so I'll give it to you anyway. It's those other occupational exposures. I know that if I have someone who has no occupational

exposure and -- because of the synergies they cause with cigarette smoking --

If I have someone who's always had a white-collar job and has never smoked, they have an extremely low incidence of lung cancer. If they've worked with exposure to asbestos or nickel or radon, or any of the other occupational exposures, their incidence of lung cancer goes up a little bit, and I'll, for the camera, show this much (indicating), okay.

If they smoke, and they're heavy smokers -- and a significant smoking history I would count as greater than 20 pack-years, which is one pack a day for 20 years; two packs a day for 10 years, however you get there, to 20 pack-years -- their incidence of lung cancer climbs 60 or 70 times what it would be without having that.

If you now put asbestos exposure, nickel exposure, radon exposure, uranium miners, et cetera -- okay -- if you combine that occupational history with a smoking history, it goes through the ceiling in terms of their risk. There's a synergy between those.

And, again, we look to this accumulation of mutations as leading to cancer. And so, if you

have it -- you know, you have it coming down one source and now you bring it in from a few other sources, you just get there earlier and frequently worse, but it's just one of many changes that go on. So I'm looking for that as part of the occupational.

Sometimes that will tip me towards trying to sort out the difference between lung cancer and mesothelioma, which is an issue at times; but, again, that's what I would use in the social history.

Q. Have you seen and/or treated patients, Doctor, who had no smoking history, but yet significant occupational exposures and who developed lung cancer?

A. Actually, I don't believe so. I think, in my -- and I have an extensive group of those patients -- I have seen a fair number of mesotheliomas in patients who are non-smokers but who had significant asbestos exposure, but I don't think I've ever seen one who just had a lung cancer with no smoking history.

Q. Do you have any other --

A. They exist. That's just my personal experience. I'm sorry.

Q. Do you have any other opinions, Doctor,

regarding the diagnosis of cancer --

A. No, I don't.

Q. -- as it relates to cigarette smoking?

A. I don't believe so.

Q. Let's move to one of the next areas, Doctor, that you --

A. Could I ask if we'd take a quick bathroom break?

Q. Of course.

THE VIDEOGRAPHER: We're off the record at 2:30.

(There was a recess from 2:30 p.m. until 2:40 p.m.)

THE VIDEOGRAPHER: The time now is 2:40. We're on the record.

BY MS. ECKELS:

Q. Doctor, I believe we had just completed covering your various opinions as it relates to the diagnosis area of your testimony. I'd like at this point to discuss with you your opinions and the basis of your opinions as it relates to causation, if I may.

What is your opinion regarding the causative or causal connection between lung cancer and cigarette smoking?

A. Smoking causes lung cancer. That's about as succinct as I can get.

Q. And are there any particular studies or texts or data which you can identify for me today that you rely upon in reaching that opinion?

A. No -- oh.

MR. SCHLESINGER: Let me do this with you, counsellor. Peculiar to the Florida Rules of Evidence are that you cannot augment your testimony with learned treatises.

If you wish to waive that, I have no objection to the doctor referring to them, relying upon them, or in any other manner expounding upon them. What's your druthers?

MS. ECKELS: Let's go off the record. I don't want to eat time discussing this.

THE VIDEOGRAPHER: It's 2:41. We're off the record.

(Discussion off the record.)

THE VIDEOGRAPHER: We're back on the record at 2:42.

MS. ECKELS: Would you read back my last question?

(The requested portion was read back by the reporter.)

THE WITNESS: No, I don't -- you know, you're asking me to take a lifetime's work and to say, "I have this opinion because of this particular paper or this particular article, and that's not the case. It's the sum and substance of 25 years of knowledge, starting all the way back in biology in college, all through medical school, all through training, all through my experience on the faculty, of all the various papers, all the various journals, all the various discussions, the thousands of conferences, et cetera, where this issue has been discussed, that leads me to my opinion of that.

I don't have a single paper, and I don't think there is a single paper or book that says, you know, "Here is the absolute." It's the sum and substance of that data that leads me to that conclusion.

BY MS. ECKELS:

Q. Are you prepared to explain today, Doctor, the medical process by which cigarette smoking, in your opinion, causes lung cancer?

A. In general terms, yes.

Q. Please explain it.

A. The -- lung cancer, like any other cancer, is the summation of a series of events that damage the genetic material of an individual cell. Now, obviously, it does it to many cells at the same time, but we're interested in that one cell that's going to become malignant.

And so, if it takes eight or ten different mutations -- and we really don't know how many it takes for lung cancer yet -- we know it's several. We've identified several of those changes to date but don't know all of them yet.

It's the summation of those that finally takes a cell over that boundary from reversibly damaged to irreversibly damaged and malignant. And that, through any number of the constituents of cigarette smoke, whether it's the benzopyrenes, the radon, all the other -- bay region diol-epoxides that are in there. All the various compounds that are in smoke have a cumulative effect on those cells. The sum of those results in lung cancer.

Whether each individual patient or each individual person has any or all of those specific changes due to each specific compound, I think is almost unknowable in its complexity; but, clearly, the sum of several of those hits, as you will, to

the genetic material of a pulmonary cell leads to the development of cancer.

And I think that -- and I'm -- in any of these -- in several areas -- for example, in colon cancer, we have six or seven genetic alterations that occur in a row, and we've identified four or five of those pretty clearly.

In lung cancer, it's at least four or five. It's probably more like eight or ten changes that we are coming up on and identifying, and we've probably identified three or four of those with some specificity. But we know that there's this accumulation of genetic changes in a certain point. That's it. That cell is irreversibly damaged, and it becomes -- it starts to grow without control.

Q. Which of these eight to ten mutations are now -- or can you describe with some specificity?

A. I think the changes that occur in the p53 gene and the ras oncogene, I think those are changes that we have with some specificity. We understand some of the other interactions but not all of them. I think that -- I mean, I can go back and refer to individual pieces of that, but I don't think we -- we don't have -- I know we don't have the full sequence of changes that lead.

We can find people who have alterations in p53 or retinoblastoma gene or in the ras gene -- or in the ras protein -- that are associated with and appear to be one of the steps. But the full sequence and how they interact with each other, we don't know yet. And in each of those, smoking has been associated with them. And, in particular, the most recent one is the changes in the p53 gene.

Q. Do these genetic changes in the lung occur in all smokers?

A. Actually, it turns out they probably do. When we look at normal tissue in smokers -- and the very earliest studies of these were actually cytologic. If we look at, for example, studies that were taken of people killed in the Korean War, and then that study has been repeated -- where people who were young kids in their early -- late teens, early twenties -- who smoked, versus those who didn't smoke and who were killed either in combat or killed in auto accidents, et cetera, the cytologic changes were far greater in the smokers. The pre-malignant changes were far greater.

If we take a patient -- and the data I'm probably most familiar with -- and look at the cellular and molecular changes in the surrounding

normal tissue of a lung -- of a patient who has lung cancer in, say, the right upper portion of the lung -- if we examine autopsy tissue from the left lower portion of the lung, the frequency of strand breaks, the frequency of mutations is far higher in smokers, and it's far higher in that distant tissue than it is in the tissue of nonsmokers.

Q. If these mutations occur, as you stated, in all smokers, then how do you account for the fact that a percentage of smokers will develop lung cancer and a percentage of smokers will not develop lung cancer?

A. Two major reasons. Number one, as I said, it's a summation of several different changes. What -- what those changes are, how many of them are required for each person is what's unclear.

For example, one of the things that we have is a capacity for what's called DNA repair. Whatever -- and you don't need DNA translated, do you? Is that all right? Can we just --

Q. That's okay.

A. -- because I can never pronounce it.

Q. That's okay.

A. As you walk down the street in the sun, as you go anyplace, you have a certain amount, as

you -- just as you go through life replicating your skin, your blood cells, your intestinal lining cells, every -- your hair, everything that you have that's growing, there will be a certain number of mutations that occur. And your ability to repair them is your DNA repair capacity, and there are a whole series of ways you do that.

But there are a series of techniques that the body uses to repair damage. If those enzymes and those systems are intact, then the number of mutations you need to incur before you get lung cancer is far greater, because you keep repairing the ones that you get.

If that's damaged -- and there are some diseases, such as xeroderma pigmentosum -- x-e-r-o-d-e-r-m-a, p-i-g-m-e-n-t-o-s-u-m -- that are characterized by a failure of DNA repair, and these people walk out in the sun. And before they go back in the house, they got a skin cancer. I mean, I'm exaggerating only slightly in that instance, but that's a DNA repair deficit.

So if the change you happen to get early on is to your DNA repair mechanisms, it only takes a couple. If your DNA repair mechanisms are in shape, you may never get there. I mean, you may never

accumulate enough changes to develop cancer.

The second piece is that a huge proportion of these people die of premature cardiovascular and pulmonary disease before they have a chance to develop lung cancer.

Q. I'm sorry. You said that last part quickly. In your opinion, the second reason is that several of them expire due to premature --

A. They die early from COPD, emphysema, coronary artery disease, peripheral vascular disease, strokes, all the things that are associated in addition with smoking. And if you -- you know, if you die at age 60 of a stroke or a heart attack or emphysema and don't live to 70, when you were going to accumulate enough genetic changes to develop lung cancer, then you don't get the lung cancer. Small consolation.

Q. One's DNA repair capacity, can that be replenished or adjusted in any way medically?

A. Very unclear. There are a whole series of questions -- from diet, from Vitamin A derivatives, from antioxidants, that whole array of preventive compounds, selenium being the most recent one of them -- that would suggest, in the premalignant phase, that you may be able to reverse

some of these changes. But once the change to a malignant cell has occurred -- once that domino flips over, you can't get that back up, and you -- there's no amount of change in DNA repair or anything else that these things would allow you to do that.

So it remains to be seen whether or not there is some benefit. We, in fact, know there's some risk. We know now that beta carotene, which everyone thought was quite benign -- if you give beta carotene to smokers to prevent the development of lung cancer, not only does it not work, but they develop more lung cancers and die earlier than people who don't take beta carotene. So we still have a very poor understanding of how those dietary and nutritional supplements impact risk. But all of that data is based on what it may do in the premalignant phase and nothing on reversing from malignant to nonmalignant.

Q. Is another possible explanation for a reason why someone with a smoking history may or may not ever contract lung cancer the genetic predisposition regarding the p53 gene, whether or not theirs is particularly strong or particularly weak?

MR. SCHLESINGER: Let me object to that question on this basis: If we're considering evidentiary considerations here, I don't think the Doctor is talking about possibilities. If you wish to talk about possibilities, that's fine, but that's not another possibility. The Doctor here is talking about what he believes causes those conditions and diseases. If you want to talk about possibilities, I have no objection, excepting when you say "another possibility." I don't think the Doctor is talking about possibilities.

BY MS. ECKELS:

Q. You can answer the question, Doctor.

A. Again, this is a summation of events. The changes in the p53 gene are not all the same. It can be -- it can be mutated in any number of different places, and those mutations have varying effects on the function of the gene and the function of its products.

And so I'm sure some of the variability is due to how much of that gene is made malfunctional and what the sum of that is, starting with -- I mean, if you just take a series of dominos. What are you born with? What are the

genetic deficits that you have in not only repairing DNA but handling compounds? I can tell you, with some certainty, that of the six of us in this room, that if you took any number of test compounds and administered them to the six of us, there would be variation on how our body handles those drugs and those compounds, detoxifies them, metabolizes them, et cetera. It's built in. Does it matter? No. It's just random variation in the genetic code.

Well, the same thing happens here. It's a random variation in those -- in those damages that occur and in how they sum up to prevent that cell from repairing itself and ultimately let it turn into a situation where it can.

So, yes, how much p53 is damaged, whether it's damaged at this locus or that locus, they're all there, and it's -- it is very complex, and we don't have every single piece of it. What we do know is if you start over here and you don't smoke and you come over here, we're going to find far fewer genetic changes and far fewer lung cancers than if you start smoking heavily over here, add that up for 20 years. The genetic changes are there and the lung cancer is on the other side of that.

Q. Would you agree with me, Doctor, that

there's still a lot to learn in the field of genetics?

A. There's a lot to learn about everything, genetics included.

Q. Okay. You listed for me earlier two reasons why, in your opinion, a smoker may not develop lung cancer, and you mentioned the DNA repair capacity and the premature death due to COPD or heart disease or such things.

Are you -- is it your testimony that those are the only two reasons?

A. No.

Q. Okay. Are you aware of any others or just -- those are the two things that you're prepared to express today?

A. Those are the ones I'm -- the ones I'm prepared to express today. I'm sure there are others. I haven't really given it a -- that's not something I've given a great deal of thought, to the "other" aspects of it.

Q. Okay. The second reason you listed, premature death due to, for instance, heart disease -- is it your testimony that that heart disease is always going to be related to a smoking history?

A. Heart disease is exactly like cancer in

this respect. It is based upon an accumulation of events. In this disease, we have isolated the genes a little bit more carefully. We know that there are some very specific genetic deficits in how we carry fats or cholesterol through the blood; that people who have them, if they have a severe case of that, are going to get premature disease, unless we take remarkable preparations to reduce their cholesterol and fat load.

On the other hand, there are a lot of variations on that that aren't quite as severe. And then, if you have that, but you always have a healthy diet and you always reduce fat and cholesterol in your diet, and you don't smoke, you're very unlikely to see heart disease.

Whereas, again, you add them all up. If you take the dietary changes and you add them together with a smoking history, you just keep adding on in a synergistic way, these changes, and you wind up with earlier and more severe cardiac -- cardiovascular disease.

Q. Do you know what percentage of smokers never develop lung cancer?

A. Yes.

Q. What would that percentage be?

A. Approximately 90 percent; high 80s to 90 percent don't develop lung cancer.

Q. Are you able to explain or to state which constituents within tobacco correlate or, in your opinion, have a causal connection to which mutations?

A. I'm not prepared to do that today. I'd have to go back and -- I mean, it's a literature that's this wide on each -- each of the compounds, and I -- and I don't follow it on a daily basis. I know it's there. I've heard the summaries of it. I've listened to the discussions of it. I know there are a whole series of them, but I -- I'm not prepared to -- wasn't prepared to discuss that today.

Q. Okay. Is it your testimony, then, Doctor, that there is -- although you may not know the names of the constituents as they link with the particular mutation --

A. Right.

Q. -- that it is possible to show, medically, the correlation of which constituent in tobacco causes which mutation within a cell that then results in lung cancer?

A. I'm not sure that we're quite that

specific in it yet. I think -- my understanding of that literature -- and, again, it's not the literature that I follow on a daily basis -- is that, clearly, smoking causes certain malignant changes now, and we've identified some of those genetic changes in p53 and other genes and what they are.

It's not clear to me that we've fully isolated which of the components in cigarette smoke does that. I know there are several candidates. I've heard discussions about that, but I don't -- it's not clear to me that we have the specific one in place.

Q. Is there any research ongoing at Moffitt which would answer that question?

A. I don't believe there is, no.

Q. Do you know of any other -- and I'm not sure if the right word is "chemicals" or "constituents" -- but are you aware of any other factors which would result in mutations other than just the constituents from tobacco?

A. Well, as I said earlier, there is a background noise of people who have no exposure to anything, ever, who will rarely get lung cancer as a fluke. Whether that's genetic or bad luck or

whatever -- I'm not sure how to describe that, but it's there.

And then, as I described, radon, asbestos, nickel -- and there are a couple of other minor ones that go down the line -- all of those have been described with small increases in the rate of lung cancer. In asbestos' case, a more significant increase in mesothelioma.

It's when those exposures, and that's -- really, any dust exposure, is how I think of it -- coal dust, cotton dust, any of those. If you get those exposures with smoking, you increase the rate of development of malignancy. But the ones that have been identified -- that was my opinion -- I mean, the ones that have been identified, in particular, include asbestos, nickel, radon, some of the various things that uranium miners are exposed to.

Q. Have you had an opportunity to fully explain your opinion regarding the causal connection, if any, between cigarette smoking and lung cancer?

A. Actually, there's one other point that I think is important --

Q. Please do so.

A. -- and germane to it, and I don't know if you're going to come to it or not. I think it has to do with an understanding that -- and I'm going to sketch again -- and I will hold it up for you.

When we look at the lung and the airways that -- wherein the cancer arises, okay? -- these airways get smaller and smaller and smaller and eventually form these little air sacs. And this area, which is called the trachea and the main bronchus, and then this area and this area (indicating) are really three distinct biologic areas of the lung. So that this area (indicating), when it becomes malignant, tends to form squamous cancers, and we call this area the central airways, the squamous zone of differentiation.

This more medium-sized airways is the secretory zone. And in that area, the things that the lung secretes -- primarily mucus that lubricates the lungs -- sorry to do that right after lunch, but that's how we lubricate our lungs and breathe, therefore -- are made in that area.

And when cells become malignant in this area, they tend to form adenocarcinomas. And when cells out in this area, which is called the respiratory zone (indicating) -- the cells out there

are very different than the cells that are in here. When these become malignant, they tend to form bronchioalveolar carcinomas, and that's -- that's one of the reasons we see that.

And in this causal role, it's this issue of how far the tobacco smoke and its products get out into the lungs that's been responsible for some of the changes we've seen in these cell types of lung cancer. We're seeing far more adenos and now bronchioalveolars in smokers, and the thought is that what's happening is -- in the old Chesterfields, if you will -- and I don't know who makes them, so I'm not picking on one, but that's the traditional non-filtered cigarette, so as I don't pick on one company or another here -- that the crap that you inhale from that deposits very early because it's large particles.

When you filter it, the smaller particles can get further out into the lung. And so you would expect, then, to see a switch from squamous to adeno just based on the filter -- on the particle size going out.

So with respect to causation and the type of pattern we're seeing, that is another point I will make either here today, as I've just done, or

under testimony.

Q. I only do so-so reading upside down.

A. Yes. It's -- I can read upside down. It's okay.

Q. You said this first area -- and I don't want to make any marks on your diagram.

A. Yes.

Q. How did you identify that first area?

A. I called that the zone of squamous differentiation. Squamous is -- are flat cells. Your skin -- the early part of your upper airway is all squamous, and that is a protective coat, to protect you from viruses and various things getting into your body.

So when that -- and when that is irritated, it gets more squamous. If you irritate your hand, you'll get a callous or a -- in that area. It thickens, and that's the response of this area.

Further down, when you irritate this area, it makes more secretions at first. And then, when it becomes malignant, it forms a glandular carcinoma or an adenocarcinoma.

Further down here, in the airways where we actually do the breathing itself, in this

so-called respiratory zone, these cells -- what they secrete is a product called surfactant, which is what infants with respiratory distress syndrome have, and --

For example, if I took and I blew bubbles into this water, those bubbles would not persist. If I put soap in there and I blew bubbles into there, those bubbles would persist. That's an issue of surface tension. And surfactant is a surface-tension agent; like soap is in this particular instance. So, absent surfactant, when you expand your lung and then collapse it, instead of coming down smoothly, it collapses like that (indicating). That's what happens to infants with respiratory distress. So now we blow surfactant down there.

Well, as these cells get irritated and become malignant, sometimes they'll produce absolutely voluminous quantities of this clear fluid, and people present with what's called bronchorrhea. They just keep coughing up clear mucus constantly with that, and that's how we've been able to distinguish the various differences.

There are immunohistochemical and molecular markers that differentiate these areas as well, and I think now a pretty good

conceptualization by basic scientists in this area of a necessity to understand these differences -- and there are gradations between them -- this is not a sharp line between them -- as you talk about the disease and its causation and why we see different patterns in these.

Q. You use the term "irritation" in the various systems. Are you using that word synonymous with the mutations of the cells?

A. No. No. If you put a chemical onto any surface, whether it's your airways or your skin or anyplace else, it will do two things. If it has the capacity to mutate, it will cause a mutation. That mutation is not accompanied by an inflammatory response, okay?

Now, if a compound can cause an inflammatory response -- that means your body says, "This is irritating. We're going to put pus cells and other things in there" -- histamine, get some fluid in there, you know, get rid of it, dilute it out of there -- that's called its ability to irritate or to cause an inflammatory response. They're frequently linked but not always. I mean, you know, bee stings are inflammatory, but they don't cause cancer and vice versa. There are some

things that are totally noninflammatory but are malignant. It has nothing to do with cigarette smoking, either, but there are -- in cigarettes they are -- they run together because it is both irritating and mutating.

Q. Okay. Would you draw "Number 2" at the bottom of that page so I'll know that that was the second drawing.

A. Surely.

Q. And do you still have the first drawing that you did?

A. I believe I do.

Q. If you would put a "1" at the bottom corner of that one.

A. Surely.

MS. ECKELS: And I'd like to have both of these marked as an exhibit to your deposition.

THE WITNESS: That's fine with me. Do you want me to hold them up -- is that 2 as well? But I'll give them as exhibits. That's fine.

THE VIDEOGRAPHER: Thank you.

THE WITNESS: You're welcome.

(The documents were marked as Ruckdeschel Exhibit Numbers 1 and 2 for identification.)

BY MS. ECKELS:

Q. With that additional testimony, have you completely explained to me your opinions regarding the causal connection, if any, between cigarette smoking and lung cancer?

A. To the best of my memory today, yes.

Q. Okay. Do you have opinions, Doctor, regarding a causal connection between cigarette smoking and any other types of cancer?

A. Yes, I do.

Q. Would you list those cancers for me and then we'll discuss the opinions for each?

A. Yes. The opinions will be the same for each, and so I'll -- I'll go into it. It is my understanding that -- and, again, these are not areas that I follow on a day-to-day basis, but only in the course of many meetings and reviews.

Most clearly, the whole array of cancers called head-and-neck cancers or upper aerodigestive cancers -- and by those I mean the tongue, the buccal -- the inside of the cheek -- the tonsils, the pharynx, the larynx, that whole area of the upper airways here, that those are clearly cigarette-related or smoking-related diseases.

That esophageal cancer has some

relationship to it. Again, that's -- you actually inhale a fair amount of air and smoke along with it. Bladder cancer and pancreatic cancer are the others that I'm most associated -- most familiar with them. I'm sure there are probably others, but those are the ones I'm most comfortable with, and it's really the same issue. Each of those organ systems -- I'm sorry. It's a little bit different issue.

Head-and-neck cancers are exactly like lung. It's a direct toxic exposure to that tissue where the balance of irritation and mutation -- those damages occur in the tissue, and the same set of -- even though they may differ in their details, it's the same summation of genetic and other occupational exposures that lead to it; and, in particular, in head-and-neck cancer, alcohol usage -- heavy alcohol usage, along with tobacco, seems to be a big problem in head-and-neck cancer. It seems to contribute as well, and there's a little bit less on occupational exposures in that area.

The other cancer -- and esophageal cancer, to the extent it's related, would be the same. Cancers like bladder cancer -- it would appear that, as some of these compounds are taken into the body or absorbed through the lungs, the

body has to get rid of them.

Now, the body can absorb through the skin or through the respiratory tract -- or the GI tract, if you eat it -- can absorb what I will call hydrocarbons or organic substances. Those are things that are soluble in alcohol, for example, or in any other organic compound.

Now, your body does not like organic compounds floating around in it. And so one of the major detoxifying systems you have -- the whole p450 system, et cetera, and a whole array of other detoxifying enzymes -- are immediately trying to convert any organic compound in your body into a water-based compound, something that is soluble in water.

For example, oil and water don't mix. In vinegar, you -- or in a salad dressing, you shake it up, okay, and you get the bubbles of one and the other. You leave it long enough and they settle out again, okay?

So what your body is saying is, we don't -- we can't have things floating around like that. So we have to convert that oil-based substance into a water-soluble substance so it stays in. That's how you detoxify everything, every drug, every

chemical. Anything you absorb is done that way.

And so what appears to happen is that you take that in; it gets absorbed; goes to the kidney and the blood flow, and that's one of the places where -- because that's how you get rid of it, is either through the kidney or through the bile duct. That's how you take organic compounds; convert them to water-soluble compounds; and get them out of the body. That's -- that's how you do it. There's -- or in the stool. I guess that's the other place you could do it.

But -- so I would look at bladder cancer as something where these compounds are absorbed. They're turned into water-soluble. They're released through the kidneys into the urine, and it sits in the bladder for one hour, two hours, however long we can go between urinating, and that's how I -- where I feel that is the relationship to it.

But that relationship -- that's only the means of exposure. The rest of it's identical. Every cancer is a summation of various pre-existing genetic defects from when you're born, plus the ones you accumulate over time, and I'm sure there were other toxins that we absorb and other chemicals that we absorb that affect the bladder and that the

smoking may be additive to.

It can happen without that. You can certainly have bladder cancers without being a smoker in the -- with other occupational exposures, but it's one of the things that contribute. I think they're all in that same pattern.

Q. When you talk about these compounds that the body has to convert into being something water-soluble, and at that point it becomes exposed to bladder -- can you identify what compound you were just talking about, Doctor?

A. Any organic compound.

Q. Can you identify for me which of these compounds are contained within tobacco products?

A. Sure. A major majority of benzopyrenes, diol-epoxides, a whole series of the compounds in there. Everything that makes up tars, okay, is an organic compound that needs to be converted to a water-soluble compound to get it out of the body.

Q. Do you believe -- or is it your opinion that there is a more remote causal connection between cancers of the bladder and cigarette smoking than there is, in your opinion, between lung cancer and cigarette smoking?

MR. SCHLESINGER: Objection as to form.

A. I believe that the pathways are identical. It's a question of exposure. When you inhale a cigarette, you're putting it directly on the upper airways and the lungs. When you absorb it in the bloodstream, some goes out the bile; some goes out the stool; and some goes out the urine. And so the amount that gets elsewhere is less.

I think if you gave the same amount of material into the bladder that goes into the lungs, you'd see the same rate of development of bladder cancer as you do of lung cancer, but it just happens that there's not as much. So I think the causality -- the causal relationship is identical, but there's a dose factor as to how much gets there.

Was I clear on that? I'm sorry if I'm not.

Q. I think so. And given the nature of how these compounds travel through the body, is the dose or the potential dose that can be -- that can interact with the bladder ever going to be equal to that that interacts with the lung?

A. No, and that's because our body handles them in different ways. You deposit some of it in fat tissue. For example, if you're exposed to DDT, I can tell you it will go to your fat tissue. It'll

go to breast milk, if you have that; it'll be stored in those cells. Some of it will be excreted through your kidneys, some through the liver; some will go out in the stool. Some you'll cough up in the process of it.

So you get different dosages, depend on that. It's impossible to get 100 percent of anything inhaled through the system into the bladder.

Q. In your opinion, are there other causes for bladder and pancreatic cancer, other than exposure to organic compounds?

A. Yes.

Q. What are the other causes for those type of cancers?

A. I think those are more specific, especially in pancreatic, specific changes in genetics, specific gene deficits in that. And, again, I don't follow that as closely, but I think the bladder, for an example, is -- any number of things can cause those changes within the bladder. So, again, it depends on where you get those compounds there.

Again, the -- whatever the sequence of genes are for pancreas and bladder cancer that we

don't understand as well -- they're not as well-studied as we have it for colon, breast and lung -- there's some sequence and there's some summation of things you're born with and some things you accumulate over life that leads to a malignant change in there.

Are all of them due to organic chemicals? Probably not. Are some of them due to other illnesses? Are some of them due to changes you're born with? Undoubtedly. What they are, I don't think we have a good understanding. I certainly don't have as thorough an understanding. My understanding is the epidemiologic data, that these are tied together, and then some of the scientific data. But, again, that's not the area that I follow every day.

Q. Expanding the question -- and this may be the same answer. But expanding the question to encompass things other than organic compounds, are there other commonly accepted causes for the bladder and pancreatic cancer?

A. I would give the same answer. They're there, but I don't -- I'm not totally familiar with all of them.

Q. Okay. Given that there are other causes,

do you have any understanding of what percentage of bladder or pancreatic cancers are attributable to cigarette smoking versus other causes?

A. I've seen that data. I just don't remember it. Again, it's not something I do every day. I wasn't -- I didn't go back and review it in preparation for this. I just don't remember it.

Q. And I don't want to hold you to any specific percentage; but in your recollection, was it a truly significant number, over half, over 25 percent, or do you even remember a range?

A. I just -- I don't remember. I don't even remember the range. I remember it being significant, but I don't remember the range.

Q. Okay. I have a series -- a similar series of questions regarding the head, neck and esophageal cancer.

Are there other, in your opinion, causes -- accepted causes of cancer other than an exposure to tobacco?

A. The esophagus, like the lung -- let me address that one first -- is an organ with different parts to it. We think of it as a tube that connects the mouth to the stomach, and it's relatively a straightforward function of just moving food in

an organized fashion to the stomach.

However, the esophagus is, again, composed of squamous cells up near the top and down near the base as it goes into the stomach. There is a tendency, especially with irritation, for it to become more adenomatous, what we call a Barrett's esophagus, over time, and those are two very different kinds of cancer that arise in the esophagus.

The Barrett's esophagus has a whole series of early molecular changes described for it. It seems to be occurring with increased frequency in middle-aged men with indigestion; totally different set of causal factors or -- not so much causal as supplementary factors as -- or perhaps causal -- as cancers of the upper esophagus, which are more likely to be related to smoking because of the inhalation of smoke.

That aside, the issues in the head and neck are really -- I mean, I would go back to the same discussion on lung cancer. Here, though, the cofactors -- the other things that come into play are not so much asbestos and nickel and radon as they are alcohol, and in selected instances where there are snuff chewers, et cetera, people who keep

that stuff -- tobacco chewers keep that stuff in the side, so the same products; it's just they're not in inhaled form. They're in liquid form.

Q. And, similarly, are you aware of any -- or do you know the statistical breakdown of the percentage of head and neck and/or esophageal cancer cases which are attributable to cigarette smoking versus other causes?

A. Yeah. I don't remember it in esophagus. In head and neck, it's -- it's way up. It's over 90 percent, again. It's an uncommon disease, an almost unheard-of disease without smoking or tobacco chewing.

Q. Have you listed or explained to me, Doctor, all of the other cancers which, in your opinion, have a causal connection to smoking?

A. You know, with the proviso that my memory isn't what it used to be, those are the ones I remember offhand today.

Q. Okay. Alternately, are there certain cancers which, in your opinion, do not have a causal connection to smoking?

A. I think that there are cancers, such as sarcomas and lymph node cancers, that -- such as Hodgkin's disease -- that I have never come across

evidence that they are in any way related to smoking, but it's possible I'm wrong and I just -- I've never -- I've never been exposed to any information to that -- to that end.

Q. What about breast cancer?

A. I -- I can't remember all the data on that. I -- you know, I have heard some people discuss the issue of whether there is a relationship and whether it's one of the things that contributes, but I really don't remember it in enough detail to comment on it.

Q. What about colon cancer?

A. Same. Same as the breast cancer answer. I'm sorry.

Q. Would it be correct to say, then, Doctor, you have no opinion as to whether or not there is a causal connection between breast or colon cancer in cigarette smoking?

A. I have no memory as to whether the data that I've seen on that would establish, in my own repertoire of opinions, a causal relationship. If I go back and prepare that and read through that area, that will probably shake my memory, if there is such information, but I didn't do that in preparation for today.

Q. In discussing the constituents or the various compounds within tobacco that you believe relate to genetic mutations, are there certain compounds or constituents that you associate with certain types of cancers?

A. The -- the list of compounds in tobacco smokers is as long as this table, so -- the list of cancers is almost as long, down there. And I cannot, as I sit here today, draw specific compounds to specific cancers. It's the -- the whole ball of wax that's in tobacco smoke, and I'm sure there are people who follow this more closely that can point to specific compounds with specific defects, but I don't follow that on a day-to-day basis.

MS. ECKELS: I'm being told we're out of tape, so I think we've got to go off.

THE VIDEOGRAPHER: The time is 3:25. This is the end of the second tape of the deposition of Dr. Ruckdeschel.

(There was a recess from 3:25 p.m. until 3:35 p.m.)

THE VIDEOGRAPHER: It's 3:35. This is the third tape of the deposition of Dr. Ruckdeschel.

THE WITNESS: Very good. It took till

the third tape, but we got the pronunciation right.

BY MS. ECKELS:

Q. Doctor, have you now had an opportunity to explain to me your opinions regarding causation between cigarette smoking and various types of cancer?

A. Yes, I believe so.

Q. Do you have any other opinions regarding a causal connection between cigarette smoking and any other types of cancer that you've yet to explain to me?

A. Not that I'm -- not that I remember today.

Q. Okay. I'd like to move on to another area that you have indicated that you are an expert and which you have expert opinions, and that is the treatment of a cancer patient.

A. (Witness nods head.)

Q. What -- and, again, I'll start off with focusing just on lung cancer and then move to others. What is the -- or what are the various types of treatment for lung cancer?

A. The -- and if we were -- if I had known this, I would just have brought the picture of it.

There's a very complex algorithm, a series of boxes. You start here with a suspicion of this. You confirm this. If it's this, you do this. If it's that, you do that, but within -- within those bounds.

The first thing you're doing is looking to see -- is if the patient is surgically resectable or not. If they can have surgery and the chances of cure from that surgery are in the 50 percent or better range, then you clearly move towards surgery. Depending on the staging findings, you may have a sense or clear data that the chances -- that the patient can have a resection, but the chances of recurrence are quite high. And so you look to add either radiation therapy or chemotherapy to that, either before or after that. All of those have been studied or are currently under study.

And if the disease is a little bit more advanced so that it is extensive within the chest, but you don't find -- even though you know, statistically, that there is microscopic disease elsewhere, but you can't see it because of the limitations of our instruments. For example, to see something on an x-ray or a scan, it has to be as big as my thumbnail. It has to be a centimeter in size.

Well, that's a few billion cancer cells. So 10,000 cancer cells in your liver or brain, someplace else, there's no test -- no image we have that can even vaguely pick them up. But I know they're there because I know 90 percent of people with this stage wind up with metastatic disease.

So if I see that, and I see it extensive in the chest so that the surgeon cannot safely remove the cancer without taking out vital organs, but I don't find it elsewhere on the testing I do, then I combine chemotherapy and radiation.

If it is extended beyond the chest, elsewhere in the body, I use chemotherapy. I will go back and I will use radiation therapy to palliate other areas that it shows up where it causes pain or pressure on a particular organ. But those are all palliative procedures. Those -- the others are the ones that I would use in an attempt to cure or to prolong life, if I can't cure.

Q. And I believe I understand you, but for the benefit of others, explain what you refer to when you use the term "palliative procedures."

A. Yes. A palliative procedure, in the way I'm using the term, is a procedure that's meant -- really, we try to balance what's -- when we talk

about the quality and the quantity of life. So when I talk about an active treatment, I'm talking about something where I'm making an attempt to increase the quantity of life that you have remaining. I would love to cure you, but if I can't cure you, if I can get you from a one-year expected survival to two or three, or from three months to one year, all of those are attempts at active treatment.

Palliative treatment is the treatment I have has no expectation that it will make you live one day longer, but whatever days you have to live will be spent far more comfortable and far more productive than not, than if I didn't treat that problem.

Q. What -- or how do you determine which of these treatments -- or which combination of them you use in a particular patient?

A. What it is, where it is. And then, from that grid of what its stage is and what the cell type is, there are usually an array of treatments that are available. By 25 years of it, by having participated and led many of the national studies in this area, by writing the text -- editing the textbook in the area, et cetera, et cetera, I have a pretty good handle on which things are either proven

or nearly conclusive, versus those that are pretty speculative, versus those that are under study, versus those that just don't plain work -- plain don't work, and so that's just on experience, and I choose it from that.

Because I'm not a research center, I always ask -- the first thing, when I determine the stage of a patient, is: Is there a study available for this patient? If it -- will we -- do we have a study so that by -- in treating this patient, I will actually learn something so they will become -- their outcome will become part of a greater body of knowledge as opposed to just being treated and it goes into my memory bank somewhere.

Q. And within your field, are there generally accepted protocols of treatment for various types of cancer?

A. Yes. There are extensive treatment algorithms, so-called guidelines, clinical guidelines. There are numerous reports of them now. The National Cancer Center's network has published them. We've published seven -- we've prepared 70 of them and published many of them. Last year at the American Society of Clinical Oncology, we presented and, hence, published, both here and in Argentina,

where they picked that up in their literature, an algorithm for how to go through this thought of managing lung cancer.

So, yes, they're out there. They're complex but they're there.

Q. And is Moffitt currently involved in any clinical trials where they are experimenting or trying different types of combinations other than the accepted protocols?

A. Yes.

Q. Okay.

A. Numerous ones.

Q. And that's not an unusual event, is it?

A. No.

Q. Okay. And that's how -- is it correct to say that that's how new protocols are formulated and new recipes, if you will, are found to treat various types of cancer?

A. That's correct, and that's uniform across all forms of cancer. Test whatever you do now against whatever you think might be better. It's the ultimate -- ultimate litmus test.

Q. Do you develop or utilize a treatment plan for a lung cancer patient that does or did have a smoking history different than one that you would

use for a lung cancer patient who did not have a smcking history?

A. Slightly, yes.

Q. In what way would they differ?

A. Again, the -- the ability -- if I remove lung tissue through surgery, either take out the whole lung or a portion of the lung, I will have, by dint of doing that, reduced the amount of pulmonary tissue they have to breathe on.

Now, when you're -- when you're young and healthy, you've probably got a tennis court full of surface area. If you peeled apart all those little air sacs and spread them out on the floor, you'd have a tennis court.

You probably don't need much more than this table size to really -- to breathe on, to walk around the room and stuff. You're not going to run any marathons on it, but that's about all you'd need to do that.

And so, if I have someone who has never smoked, then I presume that the chances of them having a significant breathing problem, so that they could not tolerate surgery, are very low. And if they have no pulmonary symptoms and they've not been a smoker and they've got something in their lung

that we're going to operate on, we may go ahead and do that without checking pulmonary functions.

Whereas, on the other hand, if they're a smoker, I need to know what their pulmonary function is before I do that.

Radiation does the same thing as surgery. It just takes a couple of months. You radiate an area of lung and it's fine for a few weeks, but within a few months that area is gone, and you've -- you've essentially destroyed it as a functioning air/gas exchange organ.

And so, I have to know, if I'm going to radiate the left upper lung, that that's not a significant portion of what they're breathing on. So if this -- this is two tables here. If one of these tables was your left upper lobe, and I either removed that surgically or killed it with radiation therapy, and this was all you had to breathe on, you'd be in very deep weeds, indeed, and on oxygen and confined to wheelchair or bed and not living a very productive existence.

Q. Given that I have certain time constraints --

A. Yes.

Q. -- to discuss things with you here today,

Doctor, is it possible, in a fairly shorthand fashion, to describe the different treatments for lung cancer, given the various cell types, or is that a truly complicated discussion that would take a lengthy period of time?

A. No. They're really the same. You treat local disease -- the only difference between them now is that we don't use surgery at all in the small cell cancers. We use it whenever we can in the non-small cell cancers.

We use radiation and chemotherapy virtually under the same guidelines in both diseases, for various permutations of local disease or locally advanced disease, and we use chemotherapy for advanced disease.

The chemos actually were fairly similar until recently, when we got available some new drugs for non-small cell. Those are just now being tested in small cell. And so actually it's been commented on in several national meetings in the last year. They've really come together, and the only real substantive difference still remains the fact that surgery is not a useful -- useful treatment for most patients with small cell. There's a little subset of tiny nodules that we don't know are small cell,

but that's about it other than that.

Q. And I believe you touched on this earlier, but now that we're on the subject of actual treatment, is there a difference in the course of treatment prescribed for a lung cancer patient depending on whether it was a primary lung versus metastasis?

A. It's totally different.

Q. Okay. And is it correct to say that that difference relates to what type of chemotherapy would be most successful on the primary organ site?

A. It's what type of treatment would make the most sense. People think of colon cancer that spreads to the lung as lung cancer. They do that mistakenly. It's colon cancer in a different spot.

The -- if it's -- again, the discussion I had about the length of the interval and the growth rate of the tumor -- if it's grown very slowly and there are only a few nodules, we may we use surgery as opposed to chemotherapy. So with those in mind, often -- most of the time with metastatic disease, it is a difference in chemotherapy, but there are situations where we would use other -- other modalities to do that, and they're very different.

Q. Other than the need for pulmonary

function testing and pulmonary function knowledge, which you just described a moment ago, are there any other ways in which you would have a treatment for a lung cancer patient with a smoking history that would differ from a lung cancer patient without a smoking history?

A. Cardiac evaluation, for all the same reasons. If you've got just enough cardiac -- it's the other half of breathing, besides the surface area of lung, is the capacity of the heart to pump the blood through the lung. And if you don't have enough and you take that out of balance so that the -- if what we had in pulmonary function was the size of this room -- not the size of the table -- we say, "Okay. Well, there's probably enough pulmonary function there for normal activity," but your heart needed every bit of that oxygen because it had narrowed coronary arteries, et cetera, and you take it down to the size of this table, that isn't going to work, either, because your heart now won't get enough oxygen, so --

I mean, those are -- and there's an interplay between those, and it's complex, but that's the fundamentals of it. So cardiac function is something we clearly watch whenever we think it's

suspiciously abnormal.

Q. Any other differences in the treatment between a lung cancer patient with a smoking history and one that does not, other than the need for the additional pulmonary function knowledge and a cardiac evaluation?

A. I think the only other difference is that it -- it's now clearly been demonstrated that people with either small cell or non-small cell who continue to smoke have an increased risk of second cancers developing and also have more -- and particularly in small cell -- have more infections and live shorter. They don't respond as well or they don't live as long on therapy as people who don't continue to smoke during that.

So I would -- I would say that a smoker, I'm going to be working with them on smoking cessation to the best that they're able to do that.

Q. Do you have any other opinions, Doctor, regarding the treatment of a lung cancer patient and how that would be affected by a smoking history?

A. No.

Q. Okay. Do you have any opinions, Doctor, regarding the course of treatment for a patient with a smoking history versus a patient without a smoking

history for other types of cancer other than lung cancer?

A. Only to the extent that any patient who has particularly poor pulmonary or cardiac function, who has to undergo surgery, is at increased risk. We all -- I mean, all of us in the room, to varying degrees, even if we had to have our appendix removed today, have a tiny risk of some catastrophe befalling us due to being anesthetized and to all the physiologic changes that go on with surgery and blood clots and all the other things, like arrhythmias and irregular heartbeats and et cetera.

Those risks go up dramatically in a smoker, of postoperative infections, cardiac irregularities, et cetera. And so to the degree that I had to perform or recommend surgery for any other cancer, if the patient was a smoker with severe emphysema or COPD or severe coronary artery disease, that would very much influence how I treated that patient.

Q. Any other opinions, Doctor, regarding treatment of a non-lung cancer patient as it relates to cigarettes or cigarette smoking?

A. Not at the moment, no. Not that I remember any.

Q. Okay. One of the other areas in which you have testified that you believe you are an expert and have expert opinions is in the management of a cancer patient. Is that correct?

I believe that's one of the ones you listed for me, yet you frown, so I believe that's one of the ones you listed earlier.

A. "Management" is a term we use for clinical management. Do you mean in the financial and economic analysis of that or what meaning do you have for "management" here?

Q. I'm referring to the clinical management.

A. Clinical management, okay.

Q. And we'll get to the financial management --

A. Okay.

Q. -- end of it later, and I'll be specific with you at that time, but I appreciate your pointing that out.

What is -- and this may vary with the various stages of cancer, I understand. But can you describe the various types of management for a cancer patient?

A. Management and clinical treatment are identical. There's absolutely no difference. You

sort out what stage they are and you manage them or treat them. They're identical terms. They're interchangeable, in that context that you've just stated. So whatever answers I gave would be identical down to that.

Q. What about, I guess, the location of treatment or management? Of the lung cancer patients which you or your group treat, do you have a feel for what percentage of them are ambulatory and are therefore being treated or managed on an outpatient basis?

A. Yes.

Q. What would that be?

A. I would say 80 -- 80 percent of our patients are treated almost exclusively on an outpatient basis.

Q. How would you describe the location of the treatment or management for the other 20 percent?

A. They require hospitalization at a point in their course; usually, for surgery; occasionally, for some complications of therapy.

Q. At any given time, are there a percentage of your patients that are at a hospice?

A. Oh, yes.

Q. Do you have a feel for what that percentage would be?

A. Well, as a medical oncologist who does lung, I probably have 15 or -- well, 10 or 15 percent of my patients in hospice at any given time. It's obviously a very fluid number because they're going out the other end of hospice on a regular basis.

Q. Do you know if hospice is a reimbursable expense under the Florida Medicaid?

A. I don't know that, offhand, come to think of it. I believe it is. It's a Medicare benefit, and so if someone -- if someone came in and did not have funding or was on Medicaid, who was diagnosed as having lung cancer, we would probably -- and who was eligible -- we'd probably look towards disability determination on them, which would be automatic; and then setting in place their Medicare benefits as well, if they were of that age, or disability benefits, depending on that piece.

I just -- I'm almost sure it is because we send Medicaid patients there, the same as we send anybody else. I don't -- I don't even -- I make no distinction.

There's a couple of really retarded HMOs

who don't cover hospice benefits; but other than that, I'm not aware of anybody that excludes them.

Q. What about at-home care or therapy? Is there a -- do you have a feel for what percentage, if any, of your patients at any one time are availing themselves or that you recommend they have some sort of at-home care?

A. Well, in a certain -- first of all, all hospice care, pretty much, is at-home care. There are a fair number of patients who are on oxygen at home, a few patients who take oral medications, but it's maybe 5 percent of patients who have any substantive component of that. I'm sorry -- in whom that's the predominant form of their therapy. Everybody has some proportion of home-care med; everybody on medications of one sort or another.

Q. And is -- is it correct to say that the at-home and/or hospice care is both for therapy and for complications arising from therapy?

A. No. Hospice care is specifically in place when you're not pursuing active therapy for the disease. Hospice care is there solely for palliative care, as we previously defined that. And so they get very rightfully upset if I start ordering chemotherapy and other aggressive

treatments in there. It's not consistent with the concept of hospice, which is that active treatment is done. It's now time to prepare for death and to make the most of what time is available.

The other home care -- it varies. Some people are -- have very slow-moving cancers. We don't have an active treatment going on. We're just treating symptoms. They can do that at home.

Others, what they do at home is an integral part of their treatment, whether it's physical therapy or respiratory therapy or antibiotics or some chemotherapies that are given by mouth.

Q. Within your practice and practice group, do you know if there is a percentage, if any, of your patients that are in a nursing home?

A. It's a very minute percentage. Occasionally -- again, I told you in the beginning that on our intake form, we identify the availability of social supports. And one of those questions has to do with, "Does anybody live with you? Do you have people to help care for you?"

And so, I would say once every month or two, I'll have a patient in whom they have no family in the area or they're estranged from their family

or -- and the other family members can't get here for various reasons, and the only place they can go is to a nursing home. There's no way to send them home. There's nobody to help care for them at home, and so they would get to a nursing home, but that's very, very uncommon.

Q. Expanding that same question beyond just your practice at Moffitt, but rather your experience on the whole with other facilities as well, would you also agree that the percentage of individuals who are lung cancer patients that are referred to nursing homes is minute?

A. Yes. Mostly because the disease, by the time they get to that phase, is going like a bat out of hell, and the patients don't live long enough to make it to a nursing home.

Q. Do you have any other opinions, Doctor, that relate to the field or the area of management -- I know you've told me that's basically identical to treatment -- of a lung cancer patient as it relates to any particular aspects, if they have a smoking history?

A. No. Given that proviso of what we call management or treatment, I don't -- I don't think so.

Q. Okay. The same question but as to other cancers outside of lung.

A. Same thing. Same thing.

Q. Okay. Another area that you have expressed expertise and the fact that you have opinions is the costs affiliated with the management of cancer patients. Is it possible -- again, within the confines of some of the time limitations we have today -- to begin to outline or express for me what the typical costs are?

A. With the proviso that this is extremely rough and is conditioned by the time constraints we have, and there are obviously far more nuances to this. I think there's very good data nowadays -- much of it developed in Canada but a lot of it developed in the states -- and data that each of us who run institutions have to develop on a regular basis.

We know the approximate cost -- somewhere in the twenty to twenty-five thousand dollar range -- of having a patient comes in who has primarily surgical therapy. We add five or ten thousand whenever we add radiation, and we add another ten or twenty thousand whenever we add chemotherapy on sort of an average course over a period of time. Those

numbers go up when you have newer drugs.

Taxol, for example, is several thousand a treatment instead of several hundred for other treatments. So you can -- you can get up there.

I don't have the figure in front of me, but we could go through our decision support systems at the Cancer Center -- I'm sure other centers can do so as well -- to give you relatively specific average costs for patients with lung cancer.

In fact, part of our business in dealing with managed care companies is -- and the government -- is to be able to very specifically know what our costs are, so that if we offer a capitated or a discounted price to the companies, that we can meet that, that it's something we can possibly do.

Q. Are you also prepared, and do you feel you have expertise in opining on the costs affiliated with treating other kinds of cancer other than lung?

A. Yes.

Q. What other types of cancer --

A. Virtually every one; because, as Director of the Cancer Center, I see what those costs are. And, fundamentally, what we're doing in that setting is to look and say, "Where are the outliers? Are

there certain diseases, for which we've identified benchmarks, that we're way over or way under? Are there certain diseases that can be treated more cheaply with the same or better outcomes and the same or better quality of that care?" So we're constantly looking for that across the whole array of things that we do.

Q. Okay.

A. And, in fact, we've published extensively on reducing length of stay for prostate surgery, the whole business in the newspapers recently about the lymph node mapping and breast cancer was developed at our institution, so that breast cancer may, in fact, become an outpatient disease in the future without the need to do the lymph node surgery. That was all developed at our place. So we do a lot of looking at our costs.

Q. Is it really necessary to discuss costs per type of cancer, or are the costs pretty much generic whether it's bladder or pancreatic, colon?

A. No. They're very, very different.

Q, Okay.

A. Some diseases -- and, again, it's both disease-specific and it is stage-specific, so that a localized bladder cancer requires some installations

into the bladder on an outpatient basis. A localized lung cancer requires thoracic surgery. I mean, those are vastly different treatments in both cost and complexity.

So, you know, again, within your time constraints, there's lots of data on it. I'm familiar with it. I'd be happy to opine, to the best of my memory, any particular one you want, but we could spend an awful lot of time tracking this down.

Q. I understand, and I may come back to that, if I have the opportunity, but I don't think I'll be able to go into the various kinds with you today.

But let me ask you this: Is it understood, or is there a general understanding within your field that certain types of cancer are far more expensive to treat than others? And, if so, which are they?

A. Well, I think the ones that are clearly most expensive are the leukemics and any of the diseases for which we're using high-dose therapy with bone marrow transplantation. There's no question that adds a level of complexity and cost to their care that far outweighs whatever we do with

the standard combinations of chemotherapy, radiation and surgery.

Q. You -- I'm going to kind of combine areas with you for just a moment.

You mentioned earlier that you felt you had a high degree of comfort, if you will, discussing the operation and economics of the Florida Medicaid system. Do you know, within the Florida Medicaid population, what the costs of treating various kinds of cancer are?

A. I do know that. I can't recite it for you. I've seen it. I'm familiar with that data. I just -- I mean, I can't remember it offhand to give it to you; but, yes, I've seen that --

Q. Okay.

A. -- and discussed it with the state Medicaid system. We've been negotiating with them, trying to find a way to make sure these patients don't get lost in between this current shift into Medicaid HMOs, which is particularly problematic for patients with cancer.

Q. Well, without getting into -- since you don't have recall -- without getting into specific figures or numbers, do you recall what types of cancer are the most expensive or is costing the

Florida Medicaid system the most amount of money?

A. Well, that's two very -- very different questions. The most expensive are the same as they for non-Medicaid patients.

The converse of that -- the other half of your question is: Which costs Medicaid more? Well, the ones that cost more are the ones that are far more common; and, of course, that becomes lung cancer, breast cancer, because those are -- and prostate cancer. Those are, far and away, the most common diseases. So if a lung cancer costs $20,000 to treat, and I treat a thousand of them, and a bone marrow transplant is a hundred thousand dollars to treat, but I only do two of them, the bone marrow transplant was more expensive individually, but the cost to the Medicaid system was there for lung cancer or colon cancer, whichever the one is.

Q. Do you know, Doctor, if there is statistical data or a breakdown, within the Florida Medicaid population, of those who are smokers and those who are nonsmokers?

A. I presume it's there, but I just don't remember. I'm sure we have that data somewhere, but I just -- I don't remember it.

Q. Do you have an opinion, Doctor, as to

what percentage of money spent for the health care of the Florida Medicaid population is attributable to smoking and which is not?

A. Oh. Yes, I do, but I -- and I've seen those figures, but I don't -- I don't remember them offhand.

There is a -- and I've seen -- and I just don't remember the specifics of it. The tobacco-related cancers and then the proportion of pulmonary and cardiac disease that is -- is related, and I've seen that broken out someplace, but I just don't remember the date offhand. Actually, I think there is pretty good data on that.

I'm sure there are others who can regale you with the details of that, but --

Q. Do you know how -- I mean, you discussed with me earlier today how you determined which types of cancer are tobacco-related and which are not. Do you know how the Florida Medicaid system makes that determination?

A. Same way.

Q. Do you know if that --

A. They would call me. I mean, they would call -- if they were interested in making that distinction on a regular basis or on an ad hoc

basis, they would put together a panel of people that would include me. And we'd sit down and say, "These are the ones that look smoking-related. Here's the proportion that we think is there. Here's our best estimate of that."

We'd -- the state has pretty extensive resources in epidemiology, both within the state health department and within the universities for statistics, and then the clinical people who can put that together. My presumption is somewhere in this litigation, that that's already been done. I just haven't seen the final pieces of it.

Q. Okay. You presume that's been done, but are you aware of any particular panel or group that's actually done that?

A. No.

Q. On the paperwork or the standard forms that Moffitt sends in for reimbursement of cancer treatment, does it include the etiology of the cancer?

A. In general, not. You know, some days when I'm -- when we discuss it as an intellectual exercise, there's broad agreement among all of us, as specialists, that when people die of COPD or die of lung cancer, that we should be putting, on the

autopsy -- on the death certificate "Smoking Addiction" or some other discussion of their smoking history so that that flags up. But, in practice, we don't do that because there are so many things that can go on there. Smoking is one of them. It's presumed for certain of them.

We're busy; these things pop on our desk in an odd moment and we sign it, and we put down "They died of lung cancer; they died of heart disease," or whatever the specifics are. But we don't do it just because we're lazy, not because it's the right thing to do.

Q. And given that that information is not always available on data such as a death certificate, does that make the epidemiological studies based upon those certificates, then, somewhat flexible?

MR. SCHLESINGER: Objection to the form of the question.

A. Yeah, I think -- I think if a study was based solely on death certificate data, that I would always question that. People in the field always question death-certificate-only data for the kinds of things that are not on -- on there.

So when we talk about those in an

epidemiologic sense, it's because we have another data source for that, whether that's data that was collected clinically or is in the tumor registry. I think the registries collect that, but I'm -- it would come from another source.

Q. Would you agree with me, Doctor, that the most definitive way to know an exact diagnosis is typically the findings obtained through autopsy?

A. No. You know, the autopsy rates are so low nowadays that we don't -- we don't see a whole lot of them, and so -- in a day when we did not have CAT scanning and magnetic resonance imaging and the ability to do fine needle biopsies of virtually any part of the body, the autopsy was the definitive way, and often surprised us.

Nowadays, there's an occasional surprise. The need for an autopsy is much less. We have so many diagnostic things available to us that it is very uncommon that we need an autopsy to sort out what was wrong. It happens -- half a dozen patients a year, but several hundred others for me personally; several thousand others for us an institution -- that we don't really need it. We've got it absolutely locked solid what's wrong.

Q. Would you -- or are you of the opinion

that that is true for all medical facilities, or is Moffitt, perhaps, slightly unique in that situation?

A. No. I think that's -- that's becoming true. I think that's in a state of flux, okay. If you -- if you want to go back and say, "What is the absolutely definitive information," yes. I mean, having autopsy information telling you where the disease is, et cetera, that is the most definitive way to do that, to have the information. But because of those changes in medical practice and the availability of far more sophisticated diagnostic techniques, we rarely resort to it any more as a means of solving the problem. That extends across all different cancers.

Q. In those cancer cases where there is an autopsy ultimately performed, is there still a significant variance between what the death certificate shows as a cause of death and what the autopsy, actually, results -- or the findings are?

MR. SCHLESINGER: I'll object. We don't know what you're talking about, Counselor. Are you talking about bubonic plague? What do you have in mind as far as the cause of death is concerned? Broad, form. The question is speculative. It is indefinite, and certainly

doesn't have a scientific basis that one could draw any conclusions from.

If you could answer it, Doctor, you go right ahead.

THE WITNESS: Can you repeat it?

MS. ECKELS: Sure. And I believe I limited it to cancer patients.

BY MS. ECKELS:

Q. Do you -- or do you have an opinion regarding the variance between what an autopsy -- what the autopsies of cancer patients ultimately show as the cause of death versus what appears on their death certificates?

A. Yes. The -- there's very little variance on that. The number of patients in whom we put down lung cancer as the cause of death and then perform an autopsy and change that diagnosis of lung cancer, I can think of two or three in a lifetime of doing this, but that's an extremely rare situation.

What we use autopsies for and where they help us is: Was there an unusual site of metastatic disease in the brain or in the spinal cord, or some unusual spot in the body, causing symptoms that we couldn't find the source for and that we couldn't treat very well; or, more

importantly, other problems, like infections, with fungus or some unusual thing that we're not used to seeing that confused us in terms of their clinical situation?

Those are the things that autopsy will frequently show us, something different than we expected. That's where we find unexpected tuberculosis or some other problem with a patient and have to run back and get everybody tested for it and stuff, but -- but those are the situations that we see that are not -- if you see lung cancer on a death certificate, it's -- 99.9999 percent of the time it was lung cancer.

Q. Do you have any data or information regarding the age or average age of the Florida Medicaid population?

A. Oh, it's out there. I just don't remember it. Actually, I think it's quite a bit younger than the average age of populations because there are a disproportionate number of children on the Medicaid program in this state, but I don't -- I don't remember it offhand.

Q. You just mentioned children within the Medicaid program. Do you know what the breakdown is between adolescents, adults in the Florida Medicaid

population?

A. I don't remember it offhand. I've seen it, but I don't remember it.

Q. Do you have any other specific opinions, Doctor, regarding the costs of treatment and management of a lung cancer patient?

A. No, not that I remember right now.

Q. Did you have any other specific opinions regarding the costs of treating patients other than lung cancer patients as it relates to tobacco use?

A. No, same answer. Same answer.

Q. If any other opinions come to mind before the end of the deposition, I'd appreciate if you'd let me --

A. I wouldn't be --

Q. -- let me know.

A. As you know, I've been very shy about giving my opinions, so I --

Q. I can tell. I believe we've probably already covered this, Doctor, but I just want to make sure. You mentioned earlier that, in a limited sense, you do consider yourself an expert in the area of surgery and have some opinions about surgery.

A. Right.

Q. Is it correct to say that your opinions relate to when surgery is indicated and when it's not?

A. They go far beyond that; and those are, again, uniquely related to my experience with the Lung Cancer Study Group, to designing clinical research studies involving surgery, to having established the audit program for the Lung Cancer Study Group and having been to every major thoracic surgical center in the country and in Canada, and having been through their cases and discussing how to design the forms and how we were going to agree or disagree on what was done and the nuances of that. It's a relatively unique body of knowledge about surgery and radio -- about the treatment of this disease, just because of the role I've had in clinical research.

Q. When you have a patient who has been diagnosed with lung cancer but subsequently dies of a complication such as pneumonia, what do you list as the cause of death?

A. I'll put them both. If I think that the patient was dying of their lung cancer and the -- and the final straw on that camel's back was the pneumonia, I list the lung cancer. I don't even --

probably don't even list the pneumonia. Or if I do, it's an affiliated condition.

On the other hand, if a patient has been doing well with their lung cancer and has been otherwise in remission, suffers pneumonia and dies of the pneumonia, I list the pneumonia; and then, as an affiliated condition, their lung cancer or "due to" or "as a cause of," and I try to balance it in that fashion. Common sense is my usual rule.

Q. Other than opinions about when surgery is indicated and when it is not, what are your other opinions as it relates to surgery for a lung cancer patient as it relates to tobacco use?

A. I have strong and well-informed opinions about who ought to be doing that surgery, when a patient will tolerate it, what things need to be sampled during that surgery, what things can be appropriately given before or after that surgery and whether they're of any benefit, what the unique problems are caused by giving preoperative treatment, and who that should be given by, et cetera.

I mean, other than doing the surgery itself, they're pretty extensive.

Q. Are any of these other opinions that you

have regarding who should do the surgery, which patients will and won't tolerate it, et cetera -- are any of those influenced by whether or not the patient is a smoker or a nonsmoker?

A. Yes, all of them are, because they're issues related to their ability to tolerate surgery, which is directly related to their chronic obstructive pulmonary disease or their coronary artery disease.

Q. Okay. And, generally, do you have an opinion about how you differ on surgical issues between a smoker and a nonsmoker?

A. I think I've -- I've done that, but it's the issue of how much pulmonary dysfunction or cardiac dysfunction they have.

Q. Is there any other -- are there any other differences?

A. Well, yeah. They also have -- I mean, I focused on the cardiovascular and the pulmonary, but they also have vascular disease, so-called Buerger's disease, blood vessel diseases of the coronary -- not -- the cerebral vasculature and what we call peripheral vascular disease, people who've -- who, you know, have blue feet and legs and who require bypass operations. You can -- you can watch them --

their vessels constrict as they smoke. I mean, it's -- it's one of the clearly smoking-associated diseases.

And if they've got severe peripheral vascular disease or severe cerebral vascular disease, it's just another risk factor for surgery that I have to watch for.

Q. Doctor, another area which you have expressed that you believe you have expertise and expert opinions is the field of pathology.

A. That's correct.

Q. What are your opinions regarding the pathology of a lung cancer patient as it relates to tobacco use?

A. I think one of those two pieces, the second --

THE WITNESS: What were you calling this?

THE COURT REPORTER: Exhibit.

THE WITNESS: Hmm?

Q. Exhibit.

A. Exhibit. The second exhibit, I think, outlines that. It talks about where in the pulmonary tree it arises.

I have direct knowledge, both from clinically and from research, about the various

nuances of this; have been actively involved in these studies and their translation into clinical trials and how we use them; commented on them extensively in editorials and articles, so in that fashion.

Q. Doctor, I'm sure you're familiar with the terms "inter" and "intra-active variability" as it relates to pathology.

A. No, I'm not.

Q. Okay.

A. So why don't you tell me what you mean by them and I'll see if I'm familiar with them.

Q. And perhaps I'm using slightly the wrong terminology.

Is there an accepted difference between the readings of the same slides between various pathologists?

A. Um --

Q. And that's what I'm referring to when I said the -- I do believe the "intra-active variability."

A. I'm sorry. I think what you mean is intra-observer and inter-observer variability.

Q. You are absolutely right. Thank you.

A. Okay. Yes. And that's been well-studied

in this, as a matter of fact.

For many years, we used to rely on pathologists to, if you will, give the blessing for major clinical trials in lung cancer; in particular, sorting out small cell from non-small cell; and earlier on, the various types of non-small cell based upon whether it was adeno or squamous or large cell or bronchioalveolar because we thought there were bigger differences in how they -- how they did, and that that was an important characteristic.

And it turned out, over time, that when the cooperative groups began to face constraints on their funding, that they looked at certain diseases and recognized that the inter-observer variability that made a difference for clinical trials was so small on the variations in non-small cell and between small cell and non-small cell, that it was not necessary to have a proactive review of all of these, a prospective review of all these, and so we stopped doing it.

The issue is, in point of fact -- as I told you way in the beginning -- is that many of these tumors are mixed. And so, in the past -- and to this day, a pathologist who doesn't do thoracic or pulmonary pathology all the time will look at a

cancer. It'll be very, very undifferentiated. And he'll say, "Oh, God, what is this?"

And the first area he finds of either glandular differentiation or squamous differentiation, he'll say, "This is a poorly differentiated cancer with some elements of. . ." whatever -- adenocarcinoma, bronchioalveolar, whatever.

But what's clearly been demonstrated is: The longer you look, the more you will find, in any individual cancer, all three of those areas. And so if the pathologist, instead of spending two minutes to review, he looks at his heart, and "This is cancer. That's not heart. It came from the lung. It's probably a lung cancer, okay. And it looks like very undifferentiated" --

"Oh, there's a little bit of gland formation. This is an adenocarcinoma." Next. He sends a bill for that, and he's off to the next thing.

But if you do it on a research basis and you examine the whole slide very, very carefully, what you find is that the inter-observer variability goes up because people say, "Well, you know, I see all the various pieces of it," so it's poorly

differentiated with a mixed differentiation, and that's where the big differences are. It's almost never that somebody says, "I think this is squamous," and somebody else says, "It's small cell or adeno." You don't see those kinds of differences, which is why we don't require prospective review of these.

On the other -- another example, though, on lymphomas or on leukemias, where the nuances of differences in the histology is so important, before a patient can go on a study, there has to be an agreement or a central review of what that shows before the patient goes on. So it's a very different lung. It's been well-studied. We've carried that through with tens of thousands of patients on national trials, and we just -- we don't do it anymore. It's not necessary.

Q. I believe you told me earlier that you do do the immunohistochemical studies or tests at your facility at Moffitt. Correct?

A. That's correct.

Q. Does the overall pathology results have any determination as to whether or not you proceed with the immunohistochemical testing?

A. Well, the pathologist will usually make

this distinction himself or herself, based on the tissue that they see. Occasionally, we will say -- we have a clinical question that we'd like these things resolved on, and we'll ask them to do certain things.

On the other hand, the pathologist will look at a tissue and say, "Well, it could be this. I think this is small cell; therefore, I will do the following tests such as chromogranin -- c-h-r-o-m-o-g-r-a-n-i-n -- or neuron-specific enolase, e-n-o-l-a-s-e -- to sort out and prove that it's small cell. And so we do them in that fashion.

Now, what I've studied is having -- when I was at the National Cancer Institute on sabbatical -- as that panel of tests, the immunohistochemical tests, were developed -- and they were mostly developed there, and they became available to us, a whole array of these -- and not just individual tests, but clusters of tests to do these -- there was a thought on their part, and some publications, that suggested this cluster of findings -- these patients did better or they responded to chemotherapy better, et cetera.

And so we tested that in two trials that I was chairman of: One, using the Eastern

Cooperative Oncology Group data in patients with advanced disease, non-small cell disease; and all of those patients -- their slides were taken down to Bethesda. They were stained. They were read blindly, et cetera.

And in the Lung Cancer Study Group slides, all the patients with early disease who had been resected -- in ECOG, we had the small cell as well. And we ran the whole panel of immunohistochemical markers on them. It showed they don't help us any more than the basics that we do, and it was very frustrating. We thought we had a lead as to how to do that, but those particular markers were not -- did not add overall to our diagnostic capability, so I'm pretty familiar with that. I spent a lot of time on that damn study and it was negative.

Q. And I believe we agreed earlier that, in making a diagnosis of a treatment, an actual tissue sample is preferred and is frequently considered more reliable than a cytology sample.

A. In general, yes. I mean, do we make the diagnosis and do we treat patients solely on the basis of cytology? Sure. A good portion of the time. Increasingly so as our ability to stick a

very, very fine needle, under CAT scan guidance, into virtually any organ in the body is -- has increased. And the more we do that, the more we rely on cytology.

Q. And within the different types of tissues that can be obtained, is there a preference of one over another?

A. No. What you're looking for is the one that proves the thing you need to prove. If you have a huge mass in the chest, but it would be surgically removable, you don't need to biopsy that, if they've got something in the adrenal gland that's very tiny, because if the adrenal gland is positive, surgery is not indicated. So you'd biopsy the adrenal instead of the big mass -- it doesn't matter where you get it. It depends on the question you want to answer.

We could take up a lot of your remaining time with those nuances, but basically that doesn't matter.

Q. Another area which you have expressed expertise, and that you have opinions in that area, is epidemiology. Do you recall that?

A. Yes.

Q. What opinions do you have, Doctor, within

the field or area of epidemiology as it relates to the treatment of cancer patients and tobacco use?

A. I talked about the treatment that -- the epidemiology has very little to do with the actual treatment of the diseases. But to the tobacco use, to the causation of the various diseases, epidemiology, in its broadest sense, is how we make those first assumptions, and that's what sends us in the direction of looking for specific biologic facts, whether it's something in the tissue or something in the occupational exposure.

It's epidemiology that tells you that all the people that live within "X" miles of a chemical plant have -- or all the people who work in the leather industry have testicular cancer or people who work with benzene have leukemia. It's an epidemiologic study that starts you down that direction, and then you go looking for what the agent is. First, you know they're leather workers or they're chemical workers. Then you find the agent. Then you find, ultimately, that the cell is damaged; ultimately, the gene. I mean, you go down that whole pathway.

And, certainly, the thing that started this off in lung cancer was the epidemiologic

evidence about the association between smoking and lung cancer.

Q. Would you agree, Doctor, that you cannot diagnose or determine the etiology of lung cancer or any disease solely through epidemiology?

A. Oh, I don't know if that's true. I think you can get -- I think we're doing needles on -- angels on the head of a pin here on peeling these things apart.

If you say, "Can you be absolutely 100 percent forever after certain from epidemiologic evidence to causation," I don't know. I guess there's a sliver of doubt, whatever, in there. But the -- in some cases, the evidence is absolutely overwhelming and compelling, and it's what led you to the -- to look for the other pieces.

Q. The epidemiological studies that you're aware of that relate to a causal connection between cancer and tobacco use, are you aware whether or not those epidemiological studies took into account various confounding factors?

A. I don't remember them study by study, but I believe they did, and I think they looked at most of the other things that may be involved in it. And, again, it's not any individual study may or may

not have. It's the summation of those studies over 20 or 30 years that have led virtually everyone not connected with the tobacco industry to conclude that that data is pretty compelling.

Q. Are you aware of any epidemiological results or studies that focused on the Florida Medicaid population?

A. I'm not aware of any.

Q. Other than the causation opinions that you've already given me today, do you have any other opinions that relate to the field of epidemiology as it relates to cancer and the use of tobacco?

A. No. It's just a compelling body of epidemiologic knowledge.

Q. Another area that you have expressed expertise in is that of psychology and psychiatry.

A. Um-hum.

Q. Do you remember that discussion we had earlier?

A. Sure do.

Q. And I believe at that time you stated that that expertise related to the impact -- psychiatric and psychological impact -- that cancer has had regarding patients and those who treated them. Is that correct?

A. Yes, but let me make sure I clarify that so that I'm -- as I gain the thrust of this here. That expertise is in the psychological and the psychiatric issues that lead to everything from the choice to smoke or not smoke, the other issues related to behavior modification through issues of the potential impact of psychiatric or psychological variables on outcome, through all the various impacts of the cancer on the patient, on the family, on the staff treating that patient, the interactions between themselves, and then the outcomes of treatment and various decisions on the patient, and all the way through that, how it impacts on them psychologically and psychiatrically, and have actually studied and published extensively in that area; and actually chaired the National American Cancer Society's study section, the review panel that they hand out their grants on behavioral and Psychosocial -- let's see what it's called -- PBR -- Psychosocial and Behavioral Research was the committee.

And so I saw grants and materials across the entire spectrum of this area, including both traditional psychologic problems that we think of, right through to the full psychiatric diagnoses,

their extent or their lack of extent, inpatient, and right up and through issues related to cognitive functioning, the ability to think and function before, after and during treatment, and have published in many of those areas.

Q. You listed several areas just now in which the psychological or psychiatric impacts are areas in which you believe you have expertise. Did you just state that one of them was the psychological or psychiatric components of why someone smokes?

A. Yes.

Q. Okay. What are your opinions in that area?

A. Actually, I think I -- in your time constraints -- I'll be happy to go through them again, but that issue -- I'm sorry. My mistake. I was one step ahead of myself.

I think that the -- I was going to go into the discussion of why they were stopping and doing the Prochaska data again, and I apologize. I misinterpreted your question.

There are theories and concepts people have gone through with why do people pick up a habit and an addiction that they know is destructive, that

they know is harmful to their health, and what are the things that they are going through that allows them to continue to do that, and how do they rationalize that; what are the means of understanding that, so we might intervene in that process.

It would be nice if we understood that at a psychiatric/psychological level and had a way to intervene in that process. It is very clear that you can threaten the hell out of teenagers with pictures of rotted lungs and lung cancer patients smoking out of their tracheostomies, and all these other terrible consequences, and they just sort of shrug it off.

Well, understanding why that happens and why they either begin or continue to smoke is a source of continued interest in this field.

Q. And are there any conclusions in that area?

A. I don't know that we're -- no, I don't think -- in that particular area, I don't think we have conclusions, other than some of the issues about -- in a very broad, generic sense here -- that adolescents, in particular, feel they're invulnerable, and it's not just smoking behavior.

It's driving fast, drinking to excess, using drugs, sexual activity, all these things that they -- they just don't feel there's -- you know, they're going to be here forever. They don't feel mortal.

Q. When you have a lung cancer patient who you are treating and who does have a smoking history, do you think they have a different -- or do you have an opinion about whether or not they have a different psychological impact or appreciation for the fact that they perhaps contributed to their disease themselves?

A. Yeah. Actually, it's very -- we don't focus on that, because it's -- it's an issue of adding punishment to them in a way -- it's sort of a judgmental issue for them. I speak about their smoking behaviors as it might affect their children, as it may affect others in their family, but I don't usually berate them for having done that. But I would say there's a subset of patients in whom -- especially where family members have begged them for years to stop smoking -- there's a fair amount of anger and guilt on their part.

Actually, we try to move patients through that as quickly as possible. But if they're thrashing around in guilt, it frequently is

associated with thrashing around in other decisions they have to make, and so we try to get them through that period of time and get on to deal with what's in front of them and what they need to do in the future.

Q. Is there a different psychological impact on those cancer patients who have acceptance of the fact that they contributed to their disease and who intend to continue smoking?

A. Yes, and we know that. There's -- I think I mentioned that before. The studies are very clear that people with lung cancer, whether they've been surgically treated or treated for small cell with chemotherapy -- if they continue to smoke, they do worse. They live shorter and they have more complications of their therapy during that time. Very clear data. So we counsel them on that.

Now, if it comes down to a patient saying to me, "I can't -- I'm so addicted. I can't live without it," and he's got three or four months to live, okay, I'm going to look the other way. I don't -- I'm not going to beat him over the head about it.

But if this patient has been cured of one lung cancer -- particularly if it was locally

advanced or small cell, something where I think they've dodged a bullet -- and they continue to smoke, then I'll get on their case about it pretty severely, and I will really, you know, tell them that they're -- they're playing with fire again; that they dodged one bullet. That doesn't mean they're going to dodge the second one, and that they -- they should stop; and then offer them, you know, whatever resources we have available to them in terms of smoking cessation.

Q. Is there a higher percentage of acceptance -- and, again, "acceptance" -- I mean acceptance in terms of the patient accepting the fact that they've contributed to their own disease -- with --

MR. SCHLESINGER: You know, I must object to that "contributed to their own disease." That's an amorphous kind of a question, in that it doesn't delineate what you mean by "contributed to their own disease." The causation factor is clear, is smoking.

MS. ECKELS: Well, I understand it's clear to you.

BY MS. ECKELS:

Q. Let me rephrase the question, Doctor.

Do you have a percentage of patients who acknowledge that they were aware, and have been aware for a substantial period of time, of the risks of smoking, yet continue to do so?

A. Yes.

Q. Does that percentage of patients -- or is there a group within that percentage of patients who accept the fact, then, that perhaps they had a contributory role in the creation of this disease?

A. I would say 95 percent or better understand that they did it to themselves, and they have varying levels of guilt. Many of them are frustrated that they couldn't stop. Many of them are angry about that. Others are -- you know, it's the whole range of human emotions in here. Others are, "All right. You know, I did it. What can I do about it? Let's get on with life," and they make the best they can. Others berate themselves to the end.

Q. Are there a percentage of those patients -- and you just said there's 95 percent or better that had this acknowledge -- make this acknowledgement -- that tell you they're not going to quit smoking simply because they don't want to? Not that they can't, but that they don't want to?

A. Yes. It's been years since anyone -- maybe once a year -- where someone says, "I really don't believe that the cigarettes cause lung cancer." I mean, I almost never hear that anymore. 20 years ago, that was not uncommon. And, you know, the refrain then was, "Well, my Uncle Louie, who is 80, smoked all his life and he didn't get cancer; therefore, it doesn't cause cancer." But now people -- nobody says that anymore.

What they will say -- and, again, I think I just explained -- they will say, "I can't" or "I don't want to stop smoking. I either enjoy it or I can't stop because it's too stress-provoking for me." The "I can't go through the withdrawal" elements of it. "I find it too uncomfortable." And then I make a judgment about how strong I'm going to be about that. And if I think we've either cured or have a shot at curing them, I'm going to pound on them a little bit and offer them whatever resources I can. If we're talking something that's a few months of life left, you know, I'm going to leave him alone.

MR. SCHLESINGER: Just note my objection as to the relevancy as far as this particular lawsuit is concerned regarding this

consideration of what the patient's feeling is regarding whether or not he knew the consequences of smoking. As far as this lawsuit is concerned, it has no relevancy and no bearing on the issues in this lawsuit.

BY MS. ECKELS:

Q. Have you done any -- or are you aware of any statistics that break down your patients -- between those that are Medicaid patients and those that are not among those who are refusing to stop?

A. I'm not aware of any such statistics --

Q. Do you -- are you aware of any --

A. -- nor do I -- I'm sorry.

Q. Go ahead. I didn't --

A. Nor am I aware that there is a difference. I mean, I don't suspect that there's a difference based on my clinical experience, and I'm not aware of any data that anybody has collected to look at that particular question.

Q. Are you aware of any data that indicates what percentage of the Florida Medicaid population is currently -- are currently smokers?

A. I've seen that, and it's the same or a little bit higher than the population at large. But, in general, it mirrors the population at large.

Q. Do you --

A. It mirrors the population at large based on socioeconomic status. There tends to be heavier smoking among lower socioeconomic groups, lower educational groups. And so if you correct for that issue, then there's no particular difference that I know of between them.

Q. But wouldn't you agree with me, Doctor, that the Florida Medicaid population is not going to mirror the spectrum of all economic brackets like the normal population does?

A. Of course, by definition. But the point I was trying to make -- and I may have been -- I may have lacked clarity in my answer -- was that, if you look at the whole population, as a large, there's probably a modest -- modestly higher proportion of people in the Medicaid population who smoke.

If you go across a group of people who have limited income, and who even qualify for Medicaid but who choose not to take it, or whatever, I suspect that -- or educational level, as an even more important marker, you will find really no difference between Medicaid and non-Medicaid, and I think that that's where the -- that's the point I was trying to make.

Q. Is it also your opinion that the Florida Medicaid population mirrors the general population regarding the percentage of those who have stopped smoking and remained tobacco-free?

A. Well, since it's the converse of -- or the inverse of what I just said, yes, I think it's -- with the same provisos.

Q. Do you know if there is any data that breaks down whether the Medicaid costs affiliated with a former smoker is still being attributed to the fact that they have a smoking history?

A. I've not seen the actual data, but I understand there are good algorithms and equations for doing that. I think if someone has smoked for 30 years and has stopped for two weeks, that one still has a way to attribute their lung cancer, cardiac disease, pulmonary disease to their smoking history. So I think that is factored into those. I just haven't seen the exact equation and what the data is.

Q. And what, in your opinion, would be the period of cessation which needs to exist before you would start to decrease the correlation between their health care costs and the fact that they had a smoking history?

A. Yeah. I think that the -- now, you're talking about health care costs in general or cancer-related costs?

Q. Well, let's do both.

A. Yeah.

Q. Start off with cancer-related costs.

A. To come up with cancer-related costs. It's really anywhere between 10 and 15 years -- closer to 15 -- before you can say their risk has returned to the risk of a nonsmoker, per se.

For other health care costs, I think the return on investment is much faster in that area, and that, for peripheral vascular disease, strokes, chronic obstructive pulmonary disease and its exacerbations, and coronary artery disease, that all of those you see relatively prompt improvements in various health measures. And so I would expect that within two or three years of smoking cessation, you would begin to see a reduction in health care costs that was measurable and statistically sound.

Q. Have you seen a breakdown of what the various diseases or health care costs are that the State of Florida is correlating to tobacco use within its Medicaid population?

A. I've seen reports of it, but I've not

seen the actual list itself.

Q. Okay. You just stated that, in your opinion, a cessation period of 10 to 15 years returns a former smoker to the risk level of a nonsmoker. Correct?

A. That's correct.

Q. During that 10- to 15-year period, is there a lock-step decrease in their risk as they finally get to that 10- to 15-year point?

A. Yes. It's not lock-step, but it's a smooth downward trend.

Q. It decreases proportionately?

A. Yes.

Q. Do you have any other opinions, Doctor, about the psychiatric or psychological status as it relates to the Florida Medicaid population and those who have been diagnosed with cancer?

A. No, I don't.

Q. What about those who have been -- same question, but those who have been diagnosed with any other disease.

A. No.

Q. You also mentioned earlier that you believe you have expertise and also have expert opinions in the field of addiction. Do you remember

that, Doctor?

A. That's correct.

Q. For purposes of our discussion, will you define addiction?

A. My working knowledge of addiction is behavior that seeks to replicate some physical or mental or psychological response by either -- by some form of ingestion: Breathing, smoking, injecting, swallowing, whatever that is; taking a material that you know is -- that you develop certain biologic and physiologic and psychological compulsions for, and that trying to stop doing that creates physiologic and psychological problems straight through full-scale withdrawal; and that you continue to do that -- continue those behaviors despite the fact that you know that this is not a safe or a healthy behavior, which is what distinguishes being "addicted" to watching basketball games from smoking or drinking or heroin abuse or any other much more potentially lethal and harmful addiction. And I put the "addiction" to watching basketball games in quotations when I say that.

Q. What, then, in your terms -- and I'm going to confine this to medical context -- how do

you differentiate between an addiction and a habit?

A. I don't. And, again, I'm not -- I can't quote a specific paper, but I think the whole discussion in this area has centered around the issues of, you know, when does a habit kick over into an addiction? Most people have felt that it's probably not a clear boundary, and it's also not an issue of major importance; that the -- that you recognize addiction when you see it, which is all those characteristics that I gave before.

At some place, a -- some point in time, a habit, if you can actually distinguish that from an addiction -- I'm sorry. If I take something -- a behavior that ultimately is or can be addictive, and for me is addictive, it may have started as a habit, something that I did but had control over; and at some point in time it's something I have less control over, and have physiologic responses when I try to stop it. That's how I would describe the difference. I'm not sure that that's a -- I mean, that's how I would describe it.

Q. What are the physiologic responses, that you're aware of, when an individual attempts to stop smoking?

A. They get very crabby. They get

very anxious. They get diaphoretic, tachycardic. They have intense cravings to -- to have a cigarette.

Q. How does that physiologic response to an attempt to stop smoking compare to the physiological response when someone tries to stop using drugs such as heroin or cocaine?

A. Actually, it's rather similar. In fact, it's quite a bit more insidious in that -- in that it lasts longer. There's more -- it takes a longer time to get nicotine out of the system than it does -- heroin is out of your system within about 24 hours; cocaine, within a -- within a brief period as well.

The issues in addiction to that have to do with the need to repeat the pleasurable experience or deal with the other problems. But if you get someone into detoxification for a few days, you can generally -- and then in a treatment program, you can generally move forward quite well with them off of that compound. You don't have the addiction qualities to that. Whereas, cigarettes and alcohol take a significantly longer period of time; cigarettes in particular. It's very hard to -- you can't detox someone quite as rapidly as you

can from those other drugs.

And some of the physiologic responses are a little bit different in terms of secretions and effects on the bowel, et cetera, but they're not substantively different.

Q. Isn't there a substantial difference in the physical aspects of the withdrawal regarding the organ systems?

A. Well, it -- you know, I called it a nonsubstantive difference. Yeah, there is a difference in which organ systems are involved, and you certainly have more GI and more nasal and upper respiratory problems with coming off of heroin or cocaine, but the rest of the anxieties -- sweating, cravings, et cetera -- are relatively similar.

Q. Is it your testimony, Doctor, that you think it's harder to quit smoking than it is to break a drug habit?

A. Yes. Let me clarify that. In a person who wishes to stop smoking or a person who wishes to stop using drugs, that I think it's easier to stop using drugs, such as heroin or cocaine, than it is to stop smoking.

Q. Have you ever had personal involvement in a drug-abuse cessation program? Have you ever

been involved in one as a physician?

A. I've -- yes.

Q. When?

A. Early in my career and in time that I spent at the free medical clinic in Baltimore for two or three years and sort of as a volunteer there. I had numerous patients who were involved in withdrawal. And in the course of my practice, I have patients who are -- who, in addition to their cancer, have drug abuse problems that require withdrawal; and, certainly, literally thousands of people with cigarette withdrawal.

Q. Within the Florida Medicaid population, do you have an opinion as to which is a more serious financial drain on that system, the treatment for a smoking cessation or treatments for cessation from a drug addiction?

A. I think that -- I'm sorry. Did you say the costs for the cessation or the costs of those diseases?

Q. My particular question was regarding the cessation. Do you think the Florida Medicaid system is spending as much money reimbursing for cessation -- treatment of cessation from smoking versus those that are paying for treatment who are people in --

are in clinics trying to break a drug habit?

MR. SCHLESINGER: There's some predicate. If you know.

THE WITNESS: Yes. Thank you.

A. I don't have the details, but I can -- I can tell you that here, as in the rest of society, whether it's Medicaid or any other patient population -- and whoever the insurers are, there have been only moderate attempts to appropriately deal with smoking cessation as a covered benefit; that we spend a lot of money on drug abuse, mainly because we're afraid of these people because they commit violent crimes and thefts on their way to -- on their drug-seeking behavior, and people who are addicted to cigarettes don't usually go out and rob 7-Elevens, et cetera, on their way to buying more cigarettes. So we're, as a society, more afraid of it. So we spend more money on the cessation programs in there, with marginal success in some of those programs.

But, in point of fact, though, if you look at the cost to society of cocaine abuse, heroin abuse, any of those drugs, summed all together, the cost of smoking dwarfed them by several orders of magnitude.

Q. When you say that, are you taking into account the role that intravenous drug use plays in the AIDS epidemic?

A. I can tell you that in the entire history of the AIDS epidemic in the United States, fewer people have died of AIDS than die in one year of lung cancer. And so I will say with absolute and utter and profound certainty that, whether you add in every single case of AIDS related to drug abuse in this state or any other state, that the costs associated with lung cancer dwarf -- absolutely dwarf those associated with drug addiction and AIDS.

Q. Is it your belief that the habit of smoking to society has the same detrimental effect as drug use?

A. I think it has a far greater detrimental effect. I think that the detrimental effect of drug abuse is overwhelmingly on the people who use the drugs and those who are unfortunate enough to be near them where they can steal whatever they need to support their habits.

But the cost of that -- and that's very dramatic. I mean, I don't really want to down-play that at all. I mean, it's obviously something that we're petrified of. We avoid those areas of cities

and towns. We hate it. It's a plague on our society.

But if you look at the actual dollar value of that compared to what we have to spend to take care of the lung disease, the heart disease, and the cancer related to cigarette addiction and cigarette smoking, it's minuscule compared to that.

Q. You stated a moment ago that it is your opinion that the Texas -- I'm sorry -- Florida Medicaid program spends more on drug cessation than it does on tobacco cessation. Correct?

A. That's correct.

Q. I'd like to ask a similar question but not limit it to cessation programs. Do you have an opinion whether the Florida Medicaid program spends more on drug-related illnesses versus tobacco-related illnesses?

MR. SCHLESINGER: Note my objection to that as far as relevancy is concerned.

You can go ahead and answer it, Doctor.

A. Yes. I -- in keeping exactly with what I just said, the amount of money spent by the State of Florida for tobacco-related illnesses absolutely dwarfs what it spends on drug-related illnesses.

Q. When you make that -- when you state

that opinion, are you including the moneys spent by the Florida Medicaid program to treat AIDS when you talk about drug-related illnesses?

A. Yes. Remember, I ran the AIDS unit for several years in Albany. I know the cost of that. I know that there's a new wrinkle in that in terms of the protease inhibitors that we have available, but they're very limited in what people are being offered. So those costs really haven't hit -- hit the system fully yet.

But even with the previous AIDS drugs, we spend gargantuan more money on tobacco-related -- and just orders of magnitude -- hundredsfold more money on tobacco-related diseases than we do on drug-related diseases.

Q. Let's talk about individual patients for a moment. We touched on this earlier in a different context.

You gave me some figures earlier about the costs of treatment for a lung cancer patient, generally: Radiation, the cost of chemotherapy, et cetera.

Are you also familiar with the costs of treating an AIDS patient?

A. Yes.

MR. SCHLESINGER: Again, objection. We're not -- we're not in this -- this is not an AIDS case. This is a smoking-related-disease matter and the manner in which it impacts the Medicaid system in the State of Florida. I object to it on the basis of relevancy and materiality.

You can answer if you can, Doctor.

BY MS. ECKELS:

Q. Let me finish the question first.

In comparing the costs between the two for a typical one-year period, do you have an opinion as to which is more expensive, the treatment for a lung cancer patient or the treatment for an AIDS patient?

MR. SCHLESINGER: Same objection. This -- this has absolutely no relevancy to --

MS. ECKELS: Your objection is on the record.

MR. SCHLESINGER: Counselor, don't interrupt me when I'm speaking.

MS. ECKELS: Well, you interrupted me a moment ago, so --

MR. SCHLESINGER: This has absolutely no relevancy, no materiality, no bearing on any of

the issues in this lawsuit.

BY MS. ECKELS:

Q. You can answer the question, Doctor.

A. The issue is the one I explained to you before about the bone marrow transplantation.

For an individual AIDS patient, especially if they should go on protease inhibitors, the cost of that treatment is probably substantially more than it is for an individual lung cancer patient. But a thousand lung cancer patients at $50,000 are going to cost us a heck of a lot more than 50 or 100 AIDS patients on protease inhibitors for the state and -- that was an example. I don't know that those are the numbers, per se, but -- but I use that as an example, again. So the unit cost may be higher for an individual patient, but the volume of tobacco-related disease, when you put it all together -- again, the numbers are staggering; and, therefore, even if the cost of taking care of an AIDS patient is 10 times what it is taking care of a tobacco-related disease patient, the fact that there are thousands of times more of those patients, in total cost, just dwarfs it.

Q. But have you seen any breakdown as to how that -- those two populations, those being treated

for lung cancer and those being treated for AIDS, appears within the Florida Medicaid population?

A. No. I'm generally familiar with it, but I've not seen the specifics of it.

Q. Are you prepared, then, to give any testimony which is truly costing the Florida Medicaid system more money, the money they're reimbursing for the treatment of lung cancer patients or the money they're reimbursing currently for AIDS patients?

MR. SCHLESINGER: Same objection. No relevancy. No materiality. No bearing on any of the issues in this lawsuit.

BY MS. ECKELS:

Q. You can answer the question.

A. Given the fact that you have asked me about that, and that that might be a source of questioning in the future, and that I have expertise in what the program covers or doesn't, I'll probably go look for what that data is within the Florida Medicaid system, so I would expect to be able to testify on that in -- with some specificity. I can just give you the general answer that I've already given you.

MR. SCHLESINGER: Just for the record,

Dr. Ruckdeschel, I don't think any court will call upon you to do that.

BY MS. ECKELS:

Q. Do you have any knowledge, Doctor, what percentage of the Medicaid population has been diagnosed with both cancer and AIDS?

A. I don't know it specifically for the Florida Medicaid population, but we were actually the first group in the country to report the increased incidence of lung cancer in AIDS patients back in the late 1980s when we first saw that beginning to come up. And the proportion of AIDS patients who go on to develop malignancies and die of that malignancy as opposed to die of their AIDS is well under 50 percent. I don't remember the number offhand. I'm going to think 20, 25 percent, but even that's a high estimation of that.

I have not looked to see what it is this year in the Florida population. But having run an AIDS unit, having defined the -- written the first paper to describe that correlation and published several other papers on increased risk of breast cancer, or whatever, in AIDS patients, that's my remembrance of it.

Q. And is it your testimony that there's

a high correlation between the two?

A. No, it's -- actually, there's a moderate correlation with the development of disorders of the lymph system, which is, of course, the structural manifestation of your immune system, that happens in your lymphatic system. That's the system that is disordered in AIDS. It's been attacked by the virus in AIDS, and therefore we see a fair number of lymphomas.

What we noticed, however, was that we began seeing lung and breast and other cancers in a higher incidence than we expected, but that's because we had a population of 30-year-olds.

And instead of seeing one lung cancer out of that population of five or six hundred that we might have even vaguely expected, we saw eight or nine.

At the same year, we saw 200 or 300 regular lung cancer patients and several -- several hundred more COPDs and heart disease. I mean, that's the order of magnitude differences we're talking about here.

Q. But within the Florida Medicaid population, should an HIV positive patient also be diagnosed with another disease -- lung cancer, heart

disease, whatever -- do you know how they are going to be statistically categorized for reimbursement purposes? In other words, are their medical costs going to be listed as reimbursements for AIDS treatment or reimbursement for cancer treatment?

A. There's so few of them, I'm not sure anybody has solved that problem yet. I'm sure whichever one is active.

Q. Doctor, can an individual become addicted to anything?

A. No. They're usually -- it requires a physiologic response. And by that, I mean either something pleasurable or something that is arousing in some way, whether that's heart rate or mental excitement -- whatever that is -- or reduction in anxiety, some physiologic -- and I'll put it in quotation marks -- "benefit" that the subject entails. So it would be, for example, almost impossible to become addicted to water because it has no biologic activity.

You can abuse water. I mean, there are psychiatric disorders where people drink too much water, but you're not physically addicted to that.

Nicotine, on the other hand, is an extremely addictive drug -- and there are others,

of course -- but it is extremely addictive in the traditional, causing a physiologic response that is defined by the individual as pleasurable.

Q. Is there, in your opinion, an addictive personality, meaning a composite personality for an individual who is more likely to become addicted than another person?

A. Yeah. I think we have a -- a beginning understanding of this, and I think the -- the pop psychology term for that is "an addictive personality."

I think we understand now, for alcoholism and probably for heroin and cocaine addiction as well, that there may be some differences in specific receptors within the brain, as to how people handle these, that there are, in fact, genetic differences that account for some or all of the capacity to become addicted. But we certainly don't understand all of them; and, therefore, we sort of turn that around to say -- because we can't measure all of those, we call it an addictive personality, someone who has trouble with heroin, who is likely to have trouble with drinking or to have trouble with cigarette smoking as well. They lump all of those together. But I don't think that we understand the

full array of genetic deficits; nor do we fully understand the issues related to availability.

For example, if I was -- if I had a so-called addictive personality, I would have to go out of my way to find a place to get cocaine or heroin, by and large. I mean, I would have to learn a different social circle.

On the other hand, if I had an addictive personality and wanted access to cigarettes, I would probably walk 50 feet in any direction and find someone or some facility that would either give me or sell me a cigarette. So there is the issue of availability and, you know, social acceptability. I mean, if I was found smoking a cigarette, I would probably be humiliated to the extent, as the Cancer Center Director, but I don't think anybody would fire me. Whereas, if they found me using cocaine or heroin, I'd be out the door pretty quickly.

And so the fear and the compulsion not to ever try that, whether or not I had an addictive personality, is pretty significant; whereas, it's not so for cigarette smoking.

Q. And that difference between the two that you just contrasted, smoking versus heroin use, also, tends to follow the lines of use of illegal

versus legal products. Correct?

MR. SCHLESINGER: Objection; leading. Form.

BY MS. ECKELS:

Q. You can answer.

A. Yeah. I'm -- tell me more what you mean by that. I'm not -- I'm not -- I don't --

Q. Well, wouldn't you agree with me that there is a far more social stigma attached with using illegal products, for which you can be criminally prosecuted, than that attached with those that are perfectly legal products?

A. Yes. I believe there's more social stigma attached to those.

Q. Do you have an opinion, Doctor, as to what factors determine or lead an individual to becoming addicted, in your opinion, to tobacco use?

A. Yes. I think that it is a straight-forward nicotine addiction. It's been well-studied, that that's a highly-addictive compound; that that is the addicting substance within it. I think we often confuse the fact that there are frequent social accompaniments of cigarette smoking that are linked to the physiologic benefits of it; that the arousal that comes from smoking, the

sense of heightened awareness that comes with that is physiologic from the nicotine. But the fact that we have a cigarette -- or that people have a cigarette after a -- after dinner or after a drink or after sex are positive correlations that people put together with that on a regular basis, and they're -- so they have a little psychological dependence, which is very different from the physiologic dependence on nicotine, which is a -- which is the true addiction.

Q. Do you know, or are you aware of the statistics on the number of people who quit smoking annually using the method I'll call "cold turkey," meaning without going through any particular cessation program?

A. Yeah, I've seen that. I don't remember the numbers offhand. There's a substantial portion -- in fact, the majority of people who quit, quit cold turkey. They just make a decision to stop, and they have sort of minimal supports in terms of family members or others that have been through it, or semi formal means of doing that; and that it's actually a fairly -- a much smaller percentage that use nicotine patches, et cetera.

I do know, from personal observation,

of literally dozens of friends and several hundred patients over the years, that the side effects of going cold turkey are substantial and prolonged for the individuals that haven't -- that is -- it is -- I have never heard a person who's a regular smoker say it was easy to quit; never once.

Q. Do you know -- or do you not find there to be some conflict between considering smoking to be addictive when you consider the number of people each year who do go cold turkey without any help or assistance?

A. No. I think there's no -- there's absolutely no conflict at all. I mean, it's an addiction. People can stop virtually any addiction if they have a compelling reason to do so; and, you know, "compelling" is in the mind of the beholder. And so, whatever compels someone to stop smoking or stop cocaine use or stop heroin usage, it's doable. People are able to do those cold turkey. It has no bearing on whether something is addictive or nonaddictive.

Q. Do you think there is an equal success rate among those who try to go cold turkey from drug use as there is with those who attempt to go cold turkey from cigarette smoking?

A. I don't remember the numbers. My guess is it would be lower for -- for people on drug use because of all the other social things that go along with that and the strata of life that they generally tend to be in, either at upper or lower end. I mean, the folks who are high-level professionals, who are in a world of significant cocaine abuse, have a hard time coming out of that if they don't come out of that world. And the same with the people at the other end, the street addict who's addicted at that end, and it's a very -- it's a difficult world to change altogether. Changing your smoking environment -- if you've got other family members who have stopped smoking or who don't smoke, you can get to a smoke-free environment.
It's harder to do with hard drugs.

Q. In your opinion, can people become addicted to sugar?

A. No.

Q. Can you identify for me, Doctor, any other common consumable products for which you think individuals can become addicted?

A. Not off the top of my head, no.

Q. Are there degrees of addiction?

A. Well, I think I've answered that already,

and what people tend to call habituation or habits as it -- as it swings over into addiction, and when does the physiologic response -- which cigarette was it that gave you the physiologic response that you found pleasurable that you were unable to stop versus the one right before that? I'm not sure we have a way to distinguish that. So, yes, I suspect, it to the way you've -- the way you've worded that; there are degrees of addiction, but I don't think that means that -- I don't think that means anything in terms of this particular case. I mean, you start with cigarettes. As you're on your way to full addiction -- you may be on your way to addiction without being fully addicted. You may be easier to stop; there's less usage. And part of that is how much you've used, how much of it has been stored in your body fat, how much of it is stored in other tissues in your body; and, therefore, how much more comes out. So if you've had very little and very occasional usage, you might be -- you might have a reaction where you -- your hands shake a little bit for a day. But if you've been smoking for a prolonged period of time, that goes on for a long period of time.

Q. Do you agree that the setting in which

one is raised -- in other words, growing up in a household where smoking takes place -- is a factor in whether or not that individual becomes a smoker?

A. Well, it's a factor. Whether it's causative or not is not -- not at all clear.

We know that -- we see every single variation of that, as we do for other addictive behaviors, like alcohol or drug use. We see children of -- addicts of all sorts either become addicts themselves or become abstainers along the way. We see the whole array of responses to that.

So I think that that -- that is highly variable and that there's so much that goes into that, that I'm not sure it's -- I am not sure it's relevant; but, I mean, I'll be glad to pursue it if you want to.

Q. I believe you answered this earlier, but I honestly don't recall. Is it your understanding that various types of cessation treatment for a smoker is a reimbursable item under the Florida Medicaid program?

A. It's my belief. I don't know that -- I don't know that for a fact. The belief is based on the fact that I have, as I routinely do, had patients in our smoking cessation programs. Whether

we actually got reimbursed for that or not, I don't remember -- I don't know offhand. But, I mean, nobody has said, "You can't send a patient on Medicaid to a smoking cessation program," so therefore I would continue to do it.

Q. Does Moffitt actually have a smoking cessation program?

A. Oh, yes; very active.

Q. And how long has it existed?

A. Really, pretty much since the place opened.

Q. And does it have -- are you familiar with its statistics on success rate?

A. Not offhand.

Q. Do you have an opinion as to whether it's a good or bad success rate?

A. It's a good success rate. Remember, again, people who are at a -- it depends on who we're seeing. We see some patients who come there who are hard-core smokers, who are family members, who are having a terrible time with it, and have had multiple attempts, and we're really going into a whole array of psychological and hypnotic and pharmaceutical methods to try to get them to stop.

We have other people who are scared

witless by what's happened to a family member who are very easy to stop. So it's a little bit of a skewed population compared to the world at large. We have, however, committed, obviously, to a large effort in smoking cessation research.

Q. You mentioned earlier that another area in which you feel you have expertise, and have expert opinions, related to consumer behavior in marketing. Do you recall that?

A. Yes.

Q. What are your opinions, Doctor, as it relates to this matter, in the area of consumer behavior in marketing?

I'm sorry. Let me stop you for just one --

A. That was fairly broad. I have a --

MS. ECKELS: Can we go off the record for just a minute?

THE VIDEOGRAPHER: We're off the record at 5:20.

(There was a recess from 5:20 p.m. until 5:29 p.m.)

THE VIDEOGRAPHER: It's 5:29. We're back on the record.

BY MS. ECKELS:

Q. Doctor, do you have specific opinions in this matter as it relates to the consumer behavior and marketing issues?

A. Yes.

Q. And what would those opinions be, sir?

A. My opinions are that the leading cause of adolescent smoking, that affects them both individually and as a peer group, has been the marketing done by the tobacco industry; that they, in point of fact, market specifically to adolescents because there's a clear recognition that hooking a smoker as an adolescent gives them a lifetime of potential customers; that they have, in fact -- and, as the recent release of the Liggett Myers papers will presumably demonstrate, if the reports are accurate -- that they have known for a long time that they are doing that, and doing it purposefully.

I've watched that switch, the arrival of Joe Camel and the other approaches to an adolescent marketplace, and I think it's had an absolutely major detrimental impact on the disease and the problem we were controlling; and that the two areas where we've seen continued problems were the switch to women smoking, with all of the Virginia Slims and the others marketed towards women and now towards

adolescents. And so both women and now adolescents -- in particular, adolescent women -- have picked up smoking in increasing numbers, where that had been a downward trend for many years. I think that is absolutely directly related to marketing. And, consequently, if I was a marketing specialist, I would say it was very successful marketing from the perspective of sales.

Q. Have you ever published anything, Doctor, in the area of consumer behavior or marketing as it relates to tobacco products?

A. No.

Q. Have you ever taught any courses or seminars as it -- on the subject of consumer behavior in marketing in consumable products?

A. No.

Q. Have you ever drafted or authored a marketing plan yourself?

A. Yes.

Q. When?

A. The past several years, directed a marketing program to allow patients and families in this area to understand the perverse influence of the HMO industry and its manipulation of cost data and its failure to allow access to academic health

centers. I directed, designed, studied, understood, reported on, and very successfully ran a marketing campaign which outlined that and told people how -- where to call and what to do and understand most of the principles of consumer marketing; patients, of course, being -- potential patients, of course, being our consumers.

Q. Would that be a marketing plan geared more toward education as opposed to sales?

A. No. It's, quote/unquote, "sales," if you will. It's patients coming to the center. That's our source of revenue.

Q. And did you hire or retain any type of consultant or marketing or advertising firm whatsoever that assisted you in that effort?

A. Yes, we did.

Q. And who did you retain?

A. FKQ Advertising here in Tampa.

Q. And why did you feel it was necessary to retain an advertising agency in that vein?

A. Because there are elements of specificity of the process in terms of which flights on TV and radio and when to use those that are not areas of my expertise. My areas -- I've learned them through that process. But those are still technical things

that, you know, even though I know how to repair my car, I would -- I would take it to a car repairman. So even though I could design the flights of when we would do TV and newspaper ads, based on when we have peak seasons and when the -- down here, and when we have the changeover periods and the re-signing periods for HMO plans -- they come at certain fixed dates in this state. Even though I could design when those flights should be, I'd still have someone else do that. I mean, I just -- it's not my necessity to do that.

But, certainly, the concept of our focus on research and how we presented that argument was something that I designed and managed the full way.

Q. Do you think that -- or is it your opinion that your involvement in the marketing plan of Moffitt qualifies you as an expert in the field of marketing as it relates to nationwide products?

A. I didn't make that assumption. You've just made that one.

What I said -- you asked me if I'd done that -- if I had done a marketing plan, and I said I had. I think the area of expertise comes from watching multiple sources over a 20-year period, listening to literally hundreds of discussions, both

nationally and internationally, about the impact of marketing on smoking behavior, on its impact on adolescents, watching and participating in countless conferences where that was part of the discussion that went on at those conferences.

Q. Do you sit on any panels or committees whose goals or objective involve marketing of products?

A. I'm not sure what you mean by that.

Q. Any professional associations, organizations, whose principal membership involved those involved in the marketing profession or the advertising profession.

A. I don't believe so.

Q. Have you ever been involved in any type of a marketing effort, other than the one from Moffitt that you previously described?

A. Yes.

Q. What would that be?

A. Several different marketing approaches in Albany to support of academic health centers in that particular environment.

Q. Would it be correct to say that all of the marketing efforts you've been involved to have related to medical services at various facilities

that you've been affiliated with?

A. Yes.

Q. You also mentioned earlier that you believed you had expertise and had expert opinions regarding cigarette design and manufacturing. Do you recall that?

A. No. I think -- I think I recall differently. I think what I said was that I have no particular expertise in how one designs or manufactures a cigarette; but that, in point of fact, if the -- what I felt I had expertise on is that, once that design had been made, if there was a change in the flow characteristics or in the particle size coming through, that I did have expertise on what the impact was. And there's certainly no question, as I think I've outlined in Exhibit 2, that particle size related to filter porosity is important in how far out particles get within the lungs; and, secondly, that the amount of draw and the amount of nicotine in a cigarette can be moved up and down, and that individuals will balance their -- the depth of their puffs and the number of puffs they take and how far they smoke down to get to the same level of nicotine, no matter what you do to those other elements of it.

I'm familiar with those from various sources over the years in smoking cessation research.

Q. Do you have an opinion as to whether or not there are varying levels of nicotine in the various brands of cigarettes?

A. I have an opinion, yes.

Q. And that opinion would be what, sir?

A. That there are highly variable levels; and that, in part, the tobacco industry has manipulated that level.

Q. And on what do you base that opinion, sir?

A. Multiple breast reports.

Q. Anything other than the breast?

A. No.

Q. Have you ever visited a tobacco facility and observed the cigarette being manufactured?

A. No.

Q. Do you think that relying strictly on the press is a reliable source of information?

A. I think it is one source of information that I put together with other sources to draw an opinion.

Q. What other sources have you relied on?

A. Discussions with other people who are

expert in the field. I mean, it's a -- it's a common source of discussion at meetings as the revelations come out about manipulating nicotine levels.

Q. Can you name any other experts that you've had these discussions with regarding nicotine levels?

A. It's -- I mean, I'd be naming all the people in the area of lung cancer who've -- who discuss this routinely at meetings.

Q. Do you have any other opinions as it relates to -- other than varying nicotine levels and how that may affect one's desire or smoking pattern, do you have any other opinions that relate to cigarette design and manufacturing?

A. No.

Q. Have you ever published anything in the field or on the subject of cigarette design and manufacturing?

A. No.

Q. Have you ever given any speeches or seminars or presentations on the subject of cigarette design and manufacturing?

A. Not on their design and manufacturing but on the impact of that in terms of the particle sizes

it comes through, as I've already discussed.

Q. Would you feel qualified to give any type of presentation or to publish on the subjects of actual cigarette design and/or manufacturing?

A. No. Of course not.

Q. Is there a -- you've mentioned a couple of times "particle size" and "draw."

A. Um-hum.

Q. Is there a range, if you will, or can you define that further for me?

A. I can't put the actual measurements on it, but if you -- if you take -- and I've seen the filters from those machines. If you take an unfiltered cigarette, there are visible particles. If you take a filtered cigarette, it's more of a stain on that, and I -- that's what I'm talking about in particle size.

Q. Doctor, let me hand you what we'll mark as Exhibit 3.

MS. ECKELS: Here's a courtesy copy for you.

MR. SCHLESINGER: Hand it to me first. Thank you.

(The document was marked as Ruckdeschel Exhibit Number 3 for identification.)

BY MS. ECKELS:

Q. That is an "Expert Disclosure" and -- I brought an extra one for the court reporter if you need it -- that's been produced in this case.

Have you ever seen this before, Doctor?

A. No.

Q. I take it, then, since you have not seen this before, that you did not author this?

A. I gave this information to the attorneys in the course of my discussion with them.

Q. Okay. Could you read for me the last sentence of that full paragraph, under "Subject Matter and Substance of Anticipated Testimony"?

A. "He is expected to testify concerning the follow issues: diagnosis of lung cancer, treatment of lung cancer and costs of same; overall management of patients with lung cancer and that tobacco causes lung cancer and other cancers."

Q. And you have offered me opinions today on those subjects, have you not, sir?

A. That is correct.

Q. You've also, have you not, offered me opinions on various other subjects, other than these. Correct?

A. That's correct, when I was asked to.

Q. You've also offered opinions on addiction, psychiatric and psychological effects, epidemiology, pathology, et cetera. Correct?

A. That's correct.

Q. None of those areas of expertise are listed here in your Expert Disclosure, are they, Doctor?

A. No, but I've -- those are ones that you asked me about, so I responded what I knew..

Q. And I appreciate that.

MS. ECKELS: At this point, knowing that we've got less than five minutes left on the deposition, let me just make a record that this Expert Disclosure is incomplete and inaccurate; and based on this inaccurate and incomplete disclosure, this deposition was originally scheduled and agreed to a schedule of just a six-hour deposition.

It is the position of the defendants that this is an inadequate period of time in which to depose this expert, given its broad range of expertise and opinions that have been mentioned for the first time today during this deposition; and there's a strong possibility that the defendants will seek additional time

to continue this deposition so that the full range of opinions, as offered and outlined by this witness today, can be completely explored.

Having made that record, I think basically our time is up. The videographer is kind of nodding at me, saying I have about two minutes or less, so at this point, I think -- I really can't get into much more with you today, and I appreciate your time so far, Doctor.

MR. SCHLESINGER: Let the record reflect that the plaintiff has no questions.

THE COURT REPORTER: Reading and signing?

MR. SCHLESINGER: We do not waive.

THE VIDEOGRAPHER: The time is 5:42. This is the end of the third tape of the deposition of Dr. Ruckdeschel.

THE WITNESS: Very good.

MR. SCHLESINGER: I want a copy of the deposition. Do you have an ASCII disk?

THE COURT REPORTER: Yes.

MR. SCHLESINGER: I'll take that.

(The deposition was adjourned at 5:42 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, the undersigned authority, certify that **JOHN C. RUCKDESCHEL, M.D.**, personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 1th day of May, 1997.

JEAN M. WILKES, RPR-CP
Notary Public - State of Florida
My Commission No. CC 502194
Expires: 10/21/99

JEAN M. WILKES
MY COMMISSION # CC 502194
EXPIRES: October 21, 1999
Bonded Thru Notary Public Underwriters

REPORTER'S DEPOSITION CERTIFICATE WITH ACKNOWLEDGMENT

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, **JEAN M. WILKES, RPR-CP**, Certified Shorthand Reporter, certify that I was authorized to and did stenographically report the foregoing deposition; and that the transcript is a true record of the testimony given by the witness.

I FURTHER CERTIFY that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 1st day of April, 1997.

JEAN M. WILKES, RPR-CP
Notary Public - State of Florida
My Commission No. CC 502194
Expires: 10/21/99

JEAN M. WILKES
MY COMMISSION # CC 502194
EXPIRES: October 21, 1999
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